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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

IN RE NATERA PRENATAL TESTING LITIGATION

Case No. 4:22-cv-00985-JST

Hon. Jon S. Tigar

FIRST AMENDED CONSOLIDATED CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

1 **I. OVERVIEW OF THE CASE**

2 1. During a pregnancy, prenatal testing is used to determine whether the fetus presents with
3 chromosomal disorders, such as Down syndrome and other serious conditions that can result in a
4 shortened lifespan, severe medical complications, and intellectual disability. Expectant mothers and
5 their doctors rely on the results of prenatal testing to make potentially life-altering decisions, including
6 whether to continue with the pregnancy. In the past decade, purported advances in noninvasive prenatal
7 testing or NIPT have allowed companies to offer tests that they claim can detect chromosomal
8 abnormalities earlier in pregnancy, and without posing risk to the fetus, simply by testing a sample of
9 the expectant mother's blood.

10 2. Defendant Natera, Inc. markets and sells NIPT tests that screen pregnant women for
11 various chromosomal and genetic conditions affecting a baby's health. Natera markets its NIPT tests as
12 the most reliable non-invasive method of screening for genetic conditions, advertising their accuracy.

13 3. But, while NIPT testing is generally effective at screening for Down syndrome, Natera's
14 NIPT tests return false positive test results for some rare genetic conditions 85 percent of the time or
15 more—sometimes up to 98 percent. What is more, numerous studies have found that the positive
16 predictive value ("PPV")—the likelihood that a positive result is in fact correct—for Natera's NIPT tests
17 is unacceptably low—as low as 18%—for numerous genetic conditions.

18 4. A false positive on a prenatal test can wreak severe harm upon expecting parents.
19 Besides causing unnecessary anxiety, stress, and anguish about the health of the baby, a false positive
20 NIPT leads many pregnant women to undergo invasive and expensive diagnostic testing, genetic
21 counseling, and consultations with doctors specializing in high-risk pregnancies. In addition, because
22 NIPT typically is performed relatively early in the pregnancy, diagnostic testing is not always
23 immediately available to confirm the test results. In some states, diagnostic testing may not become
24 available until after the period when a pregnancy may be legally terminated, meaning some expectant
25 parents have only the results of the NIPT testing to rely on in making the extremely difficult, life-
26 altering decision of whether to proceed with a pregnancy. Even if it is available, follow-up testing is
27 highly invasive and carries a risk of miscarriage. According to a *New York Times* investigation, some
28 expectant mothers have terminated viable pregnancies based upon a false positive NIPT test result.

1 5. On April 19, 2022, citing reports that “patients and health care providers have made
 2 critical health care decisions based on results from these screening tests alone,” including “ending
 3 pregnancies,” the U.S. Food and Drug Administration (“FDA”) issued a warning to consumers that “the
 4 results of these tests may not accurately reflect whether your fetus has a genetic abnormality.”¹

5 6. Natera has known for years yet failed to disclose that its NIPT tests are susceptible to a
 6 high rate of false positives and are of little use when screening for certain rare genetic disorders. Even
 7 today, Natera continues to promote its NIPT test as a reliable detector of rare abnormalities. The
 8 message that patients receive as a consequence of Natera’s marketing is that its NIPT test produces
 9 fewer false positives than competing tests. Meanwhile Natera suppresses and fails to reveal the extent to
 10 which pregnant women and their doctors may be induced to make health decisions based on inaccurate
 11 test results.

12 7. Natera processes more than 400,000 NIPT tests each year, meaning it tests about one in
 13 ten pregnant women in the United States. Each patient understands that the results of the test will be
 14 generally reliable—which is the whole point of doing the test. Considering the numerous flaws with the
 15 test that have come to light, users of Natera’s NIPT test have not received what they paid for, and
 16 Plaintiffs and many other pregnant women have been subjected to added medical costs, as well as
 17 unnecessary stress and anxiety, due to a false positive indication of a rare disorder.

18 **II. JURISDICTION AND VENUE**

19 8. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C.
 20 § 1332 of the Class Action Fairness Act of 2005 because: (i) there are 100 or more class members, (ii)
 21 the aggregate amount in controversy exceeds \$5,000,000 exclusive of costs and interest, and (iii) there is
 22 minimal diversity because at least one plaintiff and one defendant are citizens of different states. This
 23 Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1337.

24 9. This Court has general personal jurisdiction over Defendant because its principal place of
 25 business is in this District. The Court also has specific personal jurisdiction over Defendant because it
 26 engages in substantial business in this District and Plaintiffs’ claims arise out of or relate to Natera’s
 27

28 1 <https://www.fda.gov/medical-devices/safety-communications/genetic-non-invasive-prenatal-screening-tests-may-have-false-results-fda-safety-communication>.

1 forum-related activities.

2 10. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1331 because Natera is
 3 headquartered and regularly transacts business in this district, is subject to general personal jurisdiction
 4 in this district, and therefore is deemed to be a citizen of this district. Additionally, Natera received
 5 substantial revenue and profits from its sales of NIPT tests in this district. As such, a substantial part of
 6 the events and/or omissions giving rise to the claims at issue occurred, in part, in this District.

7 **III. INTRADISTRICT ASSIGNMENT**

8 11. Assignment to the San Francisco or Oakland Division is appropriate under Local Rules
 9 3-2(c) and (d) because a substantial part of the events or omissions giving rise to Plaintiffs' claims
 10 occurred in San Mateo County.

11 **IV. PARTIES**

12 12. Plaintiff Lisa Cassinis was, at all times relevant to the claims in this action, a citizen and
 13 resident of Los Angeles, California.

14 13. Plaintiff Sara Martinez is a citizen and resident of South Pasadena, California.

15 14. Plaintiff Amanda Law was, at all times relevant to the claims in this action, a citizen and
 16 resident of Fort Lauderdale, Florida.

17 15. Plaintiff Lillian Delaurie is a citizen and resident of Glendale Heights, Illinois.

18 16. Plaintiff Laura Ashley Heryla is a citizen and resident of Nottingham, Maryland.

19 17. Plaintiff Yelena Kreynstein is a citizen and resident of Morganville, New Jersey.

20 18. Plaintiff Chelsey Stephens is a citizen and resident of Brooklyn, New York.

21 19. Plaintiff Amanda Davis is a citizen and resident of Youngstown, Ohio.

22 20. Defendant Natera, Inc. is a Delaware corporation with its principal place of business at
 23 201 Industrial Rd., Suite 410, San Carlos, California 94070.

24 **V. FACTUAL BACKGROUND**

25 A. **Prenatal Testing**

26 21. Prenatal testing is used to assess a pregnant patient's risk of carrying a child with
 27 chromosomal disorders that can affect the baby's health. When tests provide accurate information,
 28 prenatal genetic testing provides valuable information to pregnant patients about the health of their

1 unborn child. The genetic conditions these tests are directed towards can make a pregnancy non-viable
 2 or have serious impacts on the health of a surviving newborn, such as structural anomalies, intellectual
 3 disabilities, and a shortened lifespan. For example, DiGeorge syndrome is associated with heart defects
 4 and intellectual disability, and Patau syndrome is “a condition that babies often do not survive beyond a
 5 week.”²

6 22. A pregnant patient whose child has one of these conditions must confront serious
 7 questions about risks in continuing the pregnancy, the viability of the pregnancy, and the prognosis and
 8 quality of life for any surviving newborn. Some patients choose to terminate a pregnancy that has
 9 chromosomal abnormalities. One United Kingdom study in 2017 found that 63% of U.K. women with
 10 high-risk NIPT results go on to terminate their pregnancies.³

11 23. Prenatal testing generally includes both diagnostic tests and the more recently developed
 12 screening tests. NIPT is a screening test that uses a sample of a pregnant patient’s blood (which
 13 includes DNA of the fetus) to screen for a number of genetic conditions caused by an abnormal number
 14 of chromosomes.⁴

15 24. Screening tests differ from diagnostic tests in several ways. Although diagnostic tests
 16 provide much more accurate results, they are highly invasive. For example, one common diagnostic
 17 test, amniocentesis, involves insertion of a needle through the abdominal wall into the uterus to extract
 18 amniotic fluid surrounding the fetus.⁵ Another diagnostic test, chorionic villus sampling, involves
 19 testing of a sample of the placenta that is removed through the cervix or abdomen.⁶ In addition to being
 20 physically invasive, these tests are also associated with risks, including a risk of miscarriage.⁷

21 25. In contrast, screening tests are not invasive, requiring only a blood sample, and can be
 22 performed at a much earlier stage in a pregnancy. Because different states impose different time
 23 restrictions on when a pregnancy can be terminated, NIPT—which can be done much sooner in the term

26 ² <https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html>.

27 ³ M. Hill *et al.*, “Has Noninvasive Prenatal Testing Impacted Termination of Pregnancy and Live Birth
 28 Rates of Infants with Down Syndrome?,” *Prenatal Diagnosis* 37, No. 13 (2017): 1281-90.

27 ⁴ <https://www.acog.org/womens-health/infographics/cell-free-dna-prenatal-screening-test>.

27 ⁵ <https://my.clevelandclinic.org/health/treatments/4206-genetic-amniocentesis>.

27 ⁶ <https://www.mayoclinic.org/tests-procedures/chorionic-villus-sampling/about/pac-20393533>.

28 ⁷ <https://www.forbes.com/sites/ellenmatloff/2022/01/06/what-the-nytimes-got-wrong-on-prenatal-screening/?sh=94aebd037a76>.

1 than diagnostic testing—takes on additional importance. NIPT can be done as early as 9 or 10 weeks
 2 into pregnancy.⁸ These key differences make screening tests important to pregnant patients.

3 26. But screening tests generally lack the higher accuracy of a diagnostic test. The PPV of
 4 each test is the likelihood that a positive screening result is accurate—*i.e.*, that the test result is positive
 5 *and* that the fetus actually has the tested-for condition.⁹

6 27. NIPT is reasonably accurate at identifying the most common conditions like Down
 7 syndrome (approximately 1 in 700 live births).¹⁰

8 **B. The Increased Use of NIPT Testing**

9 28. Although historically only offered to patients considered to be high risk because of their
 10 age or personal or family history, prenatal screening has expanded significantly in the last decade. NIPT
 11 was developed and grew until the American College of Obstetricians and Gynecologists (“ACOG”)
 12 changed its guidance in 2020 to recommend that all pregnant patients “be offered both screening and
 13 diagnostic testing options.”¹¹ The ACOG’s guidance is that “[t]esting for chromosomal abnormalities
 14 should be an informed patient choice based on provision of adequate and accurate information, and the
 15 patient’s clinical context, accessible health care resources, values, interests, and goals.”¹²

16 29. “In just over a decade, the tests have gone from laboratory experiments to an industry
 17 that serves more than a third of the pregnant women in America. The tests initially looked for Down
 18 syndrome and worked very well.”¹³ But, as *The New York Times* reported, “as manufacturers tried to
 19 outsell each other, they began offering additional screenings for increasingly rare conditions” such as
 20 DiGeorge syndrome and 1p36 deletion.¹⁴

21 30. Adding screening tests for rarer conditions caused by genetic microdeletions—tiny
 22 pieces of missing DNA at the sub-chromosomal level—has helped companies compete in the growing

24 ⁸ <https://www.natera.com/womens-health/panorama-nipt-prenatal-screening>);
 25 <https://www.acog.org/womens-health/infographics/cell-free-dna-prenatal-screening-test>.

26 ⁹ <https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/screening-for-fetal-chromosomal-abnormalities>.

27 ¹⁰ *Id.*

28 ¹¹ *Id.*

¹² *Id.*

¹³ <https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html>.

¹⁴ *Id.*

1 market. As *The New York Times* reported, “[a]ll the screenings could run on the same blood draw, and
 2 doctors already order many tests during short prenatal care visits, meaning some probably thought little
 3 of tacking on a few more.”¹⁵ Despite no added burden on the patient or doctors for including these
 4 additional tests, the upside for testing companies was significant, increasing costs from an average of
 5 \$695 for the basic tests to \$1,349 for the expanded panel.

6 31. The market for prenatal testing was recently estimated to range from \$600 million and is
 7 growing rapidly, with the number of women taking these tests expected to double by 2025.¹⁶

8 32. Natera has become a leader of this expanding market. “Natera has performed more than
 9 two million screenings for Down syndrome since 2013. It went public in 2015, and the value of its
 10 stock has grown to \$8.8 billion.”¹⁷ Natera “said that in 2020 it performed more than 400,000 screenings
 11 for one microdeletion — the equivalent of testing roughly 10 percent of pregnant women in America.”¹⁸

12 33. The expanded panel of screening options has played a significant role in Natera’s
 13 growth, which it expects to continue. Natera’s chief executive, Steve Chapman, reportedly said at an
 14 investor conference last January, “This is a really significant moment for the microdeletions business.”¹⁹
 15 Natera’s “2020 revenues were \$391 million, and it projected its 2021 revenues to exceed \$615 million.
 16 But if more insurers begin paying for microdeletion tests, Mr. Chapman said, the potential is ‘enormous’
 17 — it could bring in up to another \$300 million every year.”²⁰

18 34. By the end of the third quarter of 2021, Chapman claimed in an earnings call that
 19 Natera’s market share in NIPT was up to 40%.²¹ In a July 2021 interview, he said Natera was “by far
 20 the market leader, testing roughly 25% of all pregnancies in the U.S. and growing rapidly.”²²

21 ¹⁵ *Id.*

22 ¹⁶ *Id.*

23 ¹⁷ *Id.*

24 ¹⁸ *Id.*

25 ¹⁹ *Id.*

26 ²⁰ *Id.*

27 ²¹ Natera, Inc. Q-4 earnings Call transcript, Nov. 4, 2021, available at
<https://www.fool.com/earnings/call-transcripts/2021/11/05/natera-inc-ntra-q3-2021-earnings-call-transcript/>.

28 ²² Paul Moss, Steve Chapman of Natera: Five Things You Need to Create a Highly Successful Startup, *Authority Magazine*, July 7, 2021, available at <https://medium.com/authority-magazine/steve-chapman-of-natera-five-things-you-need-to-create-a-highly-successful-startup-5815f3621ace>.

1 **C. Natera's Marketing of its NIPT Test**

2 35. Natera advertises its NIPT test, "Panorama," as "the most reliable way of non-invasively
 3 assessing a baby's health" and claims that Panorama is "overall the most accurate NIPT commercially
 4 available in the United States."²³

5 36. When it launched in 2013, Natera touted Panorama as "a very reliable, yet safe
 6 noninvasive prenatal test" with "no false positives for all the syndromes tested."²⁴ Given its purportedly
 7 revolutionary nature, Natera "look[ed] forward to broadly extending the full benefits of Panorama's
 8 technology" in the future.²⁵ Shortly thereafter, in 2014, Natera announced that, in addition to screening
 9 for Down Syndrome, Trisomy 18, and Trisomy 13, the Panorama test would now screen for several
 10 microdeletion syndromes, including DiGeorge, Angelman, Cri-du-chat, and Prader-Willi syndromes.²⁶

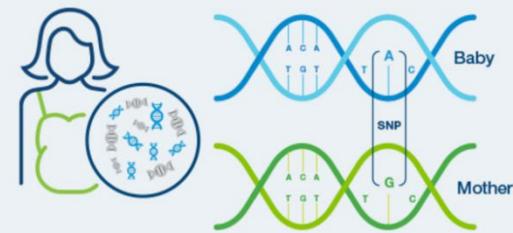
11 37. As shown below, Natera's marketing—both to patients and to doctors—highlights the
 12 test's "greater accuracy," and characterizes it as the "most reliable way of non-invasively assessing a
 13 baby's health."²⁷

14
 15 The only SNP-based NIPT delivers
 16 more insights and greater accuracy

17 Panorama is:

18 ➤ the most rigorously validated NIPT
 19 ➤ the only NIPT that distinguishes mother's DNA from baby's DNA
 20 ➤ the approach that creates unique, clinically validated capabilities

21 Panorama evaluates SNPs—the 1% of our DNA that makes us
 22 different from one another



23 ²³ Natera, Inc., 2020 10-K, Feb. 26, 2021 at 9, available at <https://investor.natera.com/sec-filings/sec-filing/10-k/0001558370-21-001907>.

24 ²⁴ <https://investor.natera.com/news-releases/news-release-details/natera-launches-non-invasiveprenatal-test-panoramatm-best-class>.

25 ²⁵ *Id.*

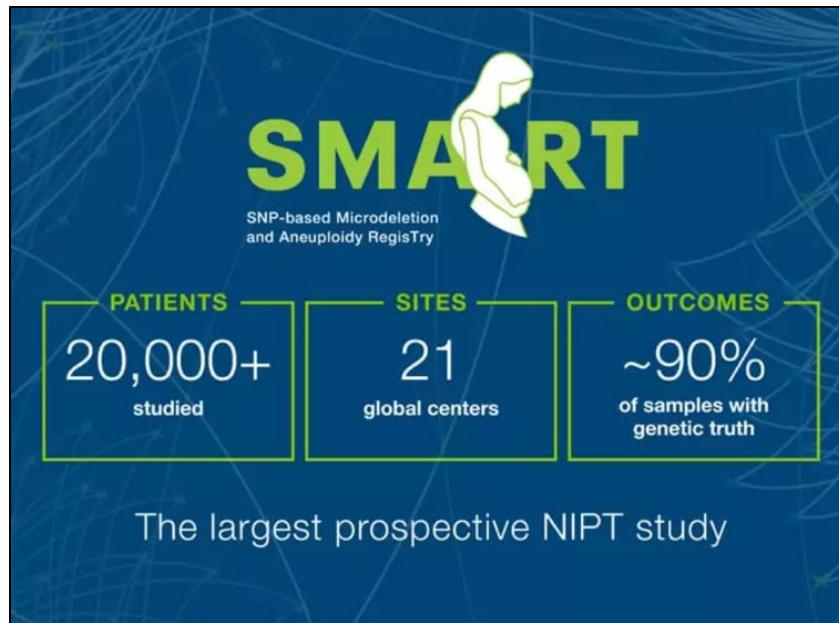
26 ²⁶ <https://www.natera.com/womens-health/panorama-nipt-prenatal-screening/>.

27 ²⁷ <https://www.natera.com/womens-health/panorama-nipt-prenatal-screening>.

1 Panorama, the #1 NIPT used in more than 3 million
 2 pregnancies, is the most reliable way of non-invasively
 3 assessing a baby's health from a single blood draw from
 4 the mother



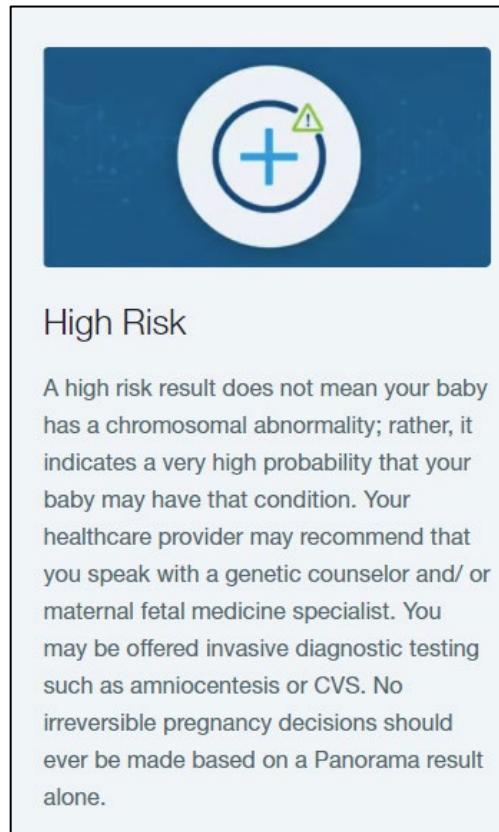
11 38. Natera's website advertises Panorama as having been tested with "the largest prospective
 12 NIPT study" with outcomes of "~90% samples with genetic truth."²⁸ The page also lists the numerous
 13 rare abnormalities Panorama screens for: Down Syndrome, Edwards Syndrome, Patau Syndrome,
 14 Turner Syndrome, Klinefelter Syndrome, Triple X Syndrome, Jacob's Syndrome, 22Q11.2 Deletion
 15 Syndrome, Prader-Willi Syndrome, Angelman Syndrome, 1p36 Deletion Syndrome, Cri-du-Chat
 16 Syndrome, and Triploidy.²⁹



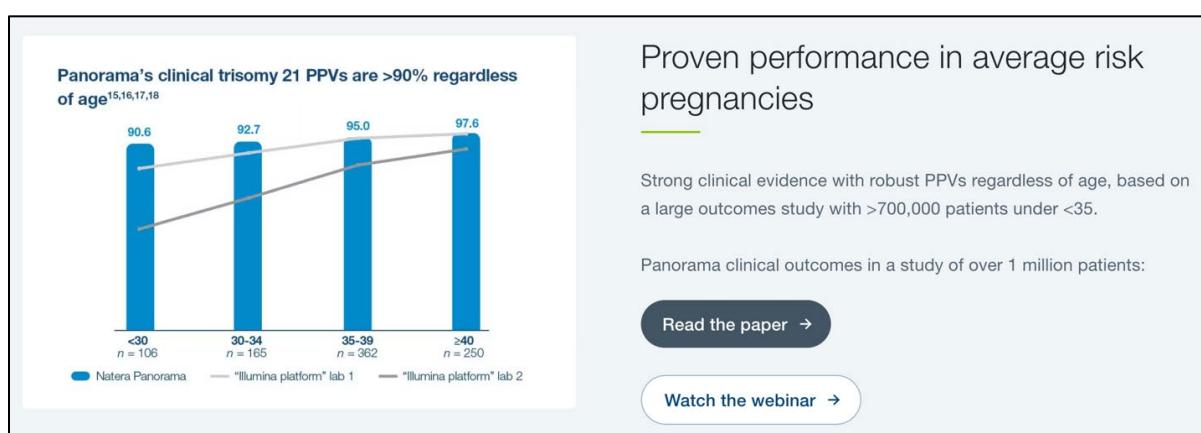
28 ²⁸ *Id.*

29 ²⁹ *Id.*

39. Panorama, according to Natera’s website, identifies whether a fetus is a “low risk” or “high risk” for genetic disease. A “high risk” finding, according to Natera, “indicates a **very high** probability that your baby may have [the] condition” identified.



40. In addition, while Natera specifically highlights the high “positive predictive value” or PPV of Panorama for Down syndrome (also known as trisomy 21), which conveys the message that its NIPT tests are accurate, it obscures that the PPV for the rarer genetic conditions Panorama screens for is as low as 2-5%.



41. Panorama's patient brochure, as of July 2021, touted that Panorama has "fewer false positives and fewer false negatives." ECF No. 31-6.

How is Panorama different?

Panorama is the only NIPT that can tell the difference between the mother's and the baby's DNA, which results in:

-  Fewer false positives and fewer false negatives^{1,2,3}
-  The highest reported fetal sex accuracy of any NIPT (fetal sex reporting is optional)^{1,2,3}
-  The ability to detect triploidy, a severe chromosomal abnormality that can result in serious pregnancy complications if unmonitored^{6,7}

42. In a similar brochure targeted at doctors, Natera makes similar claims about the accuracy of its products, boasting that its tests are “validated with >99% sensitivity & specificity.” Natera urges, “[f]or more clinically relevant information, combine Panorama, with Vistara, the next innovation in NIPT technology.”³⁰

Vistara is validated with >99% sensitivity & specificity²

nature medicine

LETTERS

<https://doi.org/10.1038/s41591-018-0334-x>

Non-invasive prenatal sequencing for multiple Mendelian monogenic disorders using circulating cell-free fetal DNA

Clinical outcomes	n
True positives	20
False positives	0
True negatives	127
False negatives	0

43. In response to the question “what are the benefits of having the Panorama prenatal screen?” on a FAQ page, Natera says: “Non-invasive and highly accurate, Panorama identifies more than 99% of pregnancies affected with Down syndrome and has the lowest reported false positive rate of

³⁰ <https://www.natera.com/resource-library/panorama/panorama-vistara-physician-brochure>.

1 any prenatal screening test for the commonly screened chromosomal abnormalities: trisomy 21, trisomy
 2 18, and trisomy 13.”³¹

3 44. Natera advertises that its NIPT test does not present the risks associated with the more
 4 accurate but invasive diagnostic tests, touting that “Panorama poses no risk to the baby compared to
 5 amniocentesis or chorionic villus sampling (CVS).”³² It also prominently advertises that its test can be
 6 performed “as early as nine weeks gestation.”³³

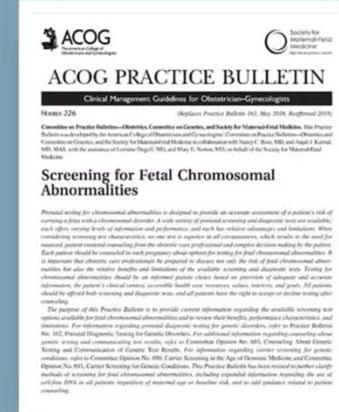
7 45. Natera also refers to recently changed ACOG guidelines, which now recommend
 8 screening be offered in all pregnancies, not just high-risk pregnancies. This recommendation increased
 9 the popularity of Natera’s NIPT tests and others on the market, but ACOG paired the recommendation
 10 with an advisory message that accurate information should be provided about the strengths and
 11 weaknesses of the various screening tests available:

12 Recent ACOG guidelines support NIPT
 13 for all pregnancies¹

14

- 15 ➤ Recommends NIPT as an option to be “discussed and offered to
 all patients early in pregnancy, regardless of maternal age or
 baseline risk.”
- 16 ➤ Endorses cfDNA as the “most sensitive and specific screening test
 for the common fetal aneuploidies.”
- 17 ➤ Highlights unique advantages of SNP-based NIPT, including
 triploidy detection and unique twins capabilities such as zygosity
 detection and individual fetal fraction measurements.

18 [Read Flipbook →](#)



20 46. On or around March 2022, approximately one month after this case was initially filed,
 21 Natera released a new version of its brochure. This version, among other things, added a QR-code link
 22 to PPVs, stated that a positive result “does not make a final diagnosis,” and removed a “peace of mind”
 23 testimonial. Even these changes, however, failed to disclose the numerous studies finding the PPV for
 24 various genetic conditions was low, and the false positive rate for various genetic conditions was high.
 25
 26
 27

28 ³¹ <https://www.natera.com/womens-health/panorama-nipt-prenatal-screening/faq/#pg-menu-tabs>.

³² <https://www.natera.com/womens-health/panorama-nipt-prenatal-screening>.

³³ *Id.*

1 47. Panorama, like other NIPT tests, is costly. Although Natera estimates that the average
 2 out-of-pocket cost for women is less than \$249,³⁴ it can often be much more expensive, costing
 3 thousands of dollars.³⁵

4 **D. The Truth About the Accuracy and Reliability of Natera's NIPT Tests**

5 48. While NIPT has recently expanded beyond Down syndrome to screen for rarer
 6 conditions, including chromosomal microdeletions, there has been a precipitous drop in the PPV of
 7 NIPT in testing for those conditions. The *New York Times* reported that NIPT for conditions associated
 8 with microdeletions such as DiGeorge syndrome (also known as 22q11.2 deletion), 1p36 deletion, Cri-
 9 du-chat syndrome, Wolf-Hirschhorn syndrome, Prader-Willi syndrome, and Angelman syndrome is
 10 wrong 81% to 93% of the time.³⁶ In addition, screenings for Triploidy, Patau syndrome (also known as
 11 trisomy 13) and Turner syndrome (also known as monosomy X) similarly generate a large percentage of
 12 false positives.³⁷ Despite the steep drop-off in the reliability of the tests and the serious implications of
 13 a positive result, Natera continues to stress their reliability.

14 49. Natera has known for years that Panorama is unreliable for microdeletion-related and
 15 other rare conditions from its own testing and external sources. In early 2016, for instance, Natera took
 16 note that data published in the January 2016 issue of *Ultrasound in Obstetrics & Gynecology* showed
 17 that Panorama had a PPV of only 18% for DiGeorge syndrome.³⁸ In that study involving high-risk
 18 cases, researchers found that diagnostic testing for 61 cases “confirmed 11 (18.0%) true positives and
 19 identified 50 (82.0%) false positives, resulting in a positive predictive value (PPV) of 18.0%.”³⁹ Natera
 20 also knows that doctors rely on company representations about the accuracy of their NIPT tests. Several
 21
 22
 23
 24

25 ³⁴ <https://www.natera.com/wp-content/uploads/2021/01/PTP-Billing-Guide-2020-English.pdf>.

26 ³⁵ <https://www.genomeweb.com/molecular-diagnostics/natera-accused-unfair-deceptive-billingpractices-related-nipt-services-new#.YdSpvmjMKUk>.

27 ³⁶ <https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html>.

28 ³⁷ *Id.*

29 ³⁸ <https://investor.natera.com/static-files/168603f8-131d-4a94-84e1-e898afdd073d>.

30 ³⁹ <https://pubmed.ncbi.nlm.nih.gov/26396068/>.

1 studies have shown that academic studies with industry involvement, as well as actual marketing
 2 materials, inform how clinicians communicate about NIPT to patients.⁴⁰

3 50. In a 2017 study entitled *Positive Predictive Value Estimates for Cell-Free Noninvasive*
 4 *Prenatal Screening From Data of a Large Referral Genetic Diagnostic Laboratory*,⁴¹ researchers
 5 analyzed the PPV and false positive rate for various conditions tested by NIPT tests like Natera's. The
 6 results did not inspire great confidence in the reliability of Panorama. For instance, the study found (i)
 7 the PPV for Trisomy 13 was 45% while the false positive rate was 55%; (ii) the PPV for Monosomy X
 8 was 27% while the false positive rate was 73%; (iii) “[t]he combined PPV for all microdeletion-positive
 9cffDNA screen cases ... was 13%”; and (iv) “the PPV for the most frequent microdeletion ...
 10 (22q11.2/DiGeorge syndrome deletion []) was 21%.”⁴²

11 51. Due to the rarity of many of the conditions tested, NIPT tests like Panorama can return
 12 more false positives than the number of test subjects who actually have the underlying condition. For
 13 instance, DiGeorge syndrome affects about one out of every 4,000 births. Thus, in a random sample of
 14 100,000 births, only about 25 would be expected to have DiGeorge syndrome, and the remaining 99,975
 15 would not.⁴³ Of that sample, a test with a “99.9% reliability” rate would thus identify about 25 true
 16 positive results (99.9% of 25) and about 100 false positives (0.1% of 99,975).⁴⁴ So, out of 125 positive
 17 test results for DiGeorge in this example, only 20 percent of the positive test results would be accurate.
 18 “This means that if an expecting mother receives a positive test for DiGeorge syndrome, there is only a
 19

20 ⁴⁰ R. M. Farrell *et al.*, “The Use of Noninvasive Prenatal Testing in Obstetric Care: Educational
 21 Resources, Practice Patterns, and Barriers Reported by a National Sample of Clinicians,” *Prenatal*
 22 *Diagnosis* 36, no. 6 (2016): 499-506; L. Parham, M. Michie, and M. Allyse, “Expanding Use of cfDNA
 23 Screening in Pregnancy: Current and Emerging Ethical, Legal, and Social Issues,” *Current Genetic*
 24 *Medicine Reports* 1, no. 5 (2017): 44-53.

25 ⁴¹ Andrea K. Petersen *et al.*, *Positive Predictive Value Estimates for Cell-Free Noninvasive Prenatal*
 26 *Screening From Data of a Large Referral Genetic Diagnostic Laboratory*, 691 AM. J. OBSTETRICS &
 27 GYNECOLOGY 1 (2017), available at <https://reader.elsevier.com/reader/sd/pii/S0002937817311870?token=89FFF7B59F5BB61B32E4961C89BE3EC80A013346930C7FE6CE514FC3FF725FC2CAF95732684F8F2A61723A4C9D285C7F&originRegion=us-east-1&originCreation=20230419200153>.

28 ⁴² *Id.* at 3.

29 ⁴³ *Id.*

30 ⁴⁴ <https://int.nyt.com/data/documenttools/the-misleading-math-of-prenatal-tests-answer-key/4ace5309f9054a76/full.pdf>.

1 20 percent chance the fetus actually has the syndrome (a far cry from 99.9 percent). In other words,
 2 there is an 80 percent chance that the test is wrong.”⁴⁵

3 52. Some of the conditions Natera’s Panorama tests for have a positive predictive value as
 4 low as 2-5%, meaning positive test results *will be wrong as much as 98% of the time*. Despite these low
 5 accuracy rates—and the significant impact the test may have on a parent’s decision whether to continue
 6 with a pregnancy—Natera promotes Panorama as reliable overall, prominently emphasizing the
 7 accuracy rates of the tests for more common conditions like Down Syndrome that Panorama can
 8 reasonably detect.

9 53. With accuracy and reliability rates this low, positive test results have little if any utility.
 10 As one obstetrician and geneticist quoted in *The New York Times* put it, “It’s a little like running
 11 mammograms on kids … The chance of breast cancer is so low, so why are you doing it?”⁴⁶

12 54. Reproductive Biomedicine & Society Online reported that patients are increasingly
 13 relying on the internet for healthcare information, which carries a corresponding increase in the risk of
 14 reliance on unclear or misleading information about NIPT.⁴⁷ The analysis found “a high degree of
 15 variability in the presentation of information about NIPT,”⁴⁸ including “most concerningly that
 16 companies, including Natera, described NIPT as a screening or diagnostic test unevenly, a key
 17 distinction for understanding the accuracy of results and easily misunderstood by patients if not
 18 presented clearly.”⁴⁹

19 55. The *Times* similarly reported that “[g]enetic counselors who have dealt with false
 20 positives say some doctors may not understand how poorly the tests work. And even when caregivers
 21 do correctly interpret the information, patients may still be inclined to believe the confident-sounding
 22 results sheets.”⁵⁰

23
 24 ⁴⁵ <https://www.nytimes.com/2022/02/10/learning/lesson-plans/the-misleading-math-of-prenatal-tests.html>.

25 ⁴⁶ <https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html>.

26 ⁴⁷ Ruth M. Farrell, Patricia K. Agatisa, *et al.*, Online direct-to-consumer messages about non-invasive
 27 prenatal genetic testing, *Reproductive Biomedicine & Society Online*, March 10, 2016, available at
[https://www.rbmsociety.com/article/S2405-6618\(16\)00003-4/fulltext](https://www.rbmsociety.com/article/S2405-6618(16)00003-4/fulltext).

28 ⁴⁸ *Id.*

⁴⁹ <https://www.documentcloud.org/documents/21179846-cfa-sec-natera-letter>.

⁵⁰ <https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html>.

1 **E. Reporting and Scrutiny of the NIPT Industry**

2 56. In January 2022, the *Times* reported widespread misrepresentations on the accuracy of
 3 NIPT. The *Times*' analysis found that approximately 85% of the time, positive results from tests
 4 screening for rare chromosomal microdeletion disorders such as DiGeorge and Prader-Willi syndromes
 5 were incorrect.⁵¹

6 57. The *Times* also reported that companies offering NIPT were not transparent about the
 7 true accuracy of their tests. “The *Times* reviewed 17 patient and doctor brochures from eight of the
 8 testing companies, including Natera, Labcorp, Quest and smaller competitors. Ten of the brochures
 9 never mention that a false positive can happen. Only one mentioned how often each test gets positive
 10 results wrong.”⁵²

11 58. The market for NIPT is not heavily regulated. “There are few restrictions on what test
 12 makers can offer. The FDA often requires evaluations of how frequently other consequential medical
 13 tests are right and whether shortfalls are clearly explained to patients and doctors. But the FDA does not
 14 regulate this type of test.”⁵³

15 59. Patients and doctors are easily confused by the marketing of companies like Natera.
 16 According to the *Times*, a former FDA official “reviewed marketing materials from three testing
 17 companies and described them as ‘problematic.’” As he put it, “These numbers are meaningless.”⁵⁴

18 60. After the *Times* released its report, Natera continued to insist that its NIPT test is
 19 accurate and reliable. On January 3, 2022, Natera issued a press release disputing the report’s analysis,
 20 insisting that its Panorama test is accurate in over 99% of cases.⁵⁵ During a February 24 conference call
 21 Natera’s chief executive similarly claimed that Panorama test results are accurate more than 99.9% of
 22 the time for both high and low risk patients.

23 61. Also in January 2022, the Campaign for Accountability sent a letter to the U.S.
 24 Securities and Exchange Commission (“SEC”) detailing the misleading nature of NIPT marketing and

26

⁵¹ *Id.*

27 ⁵² *Id.*

28 ⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ <https://www.natera.com/company/nat-news/recent-news-coverage/>; but see *id.* (acknowledging that “Natera’s microdeletion test has PPVs ranging from ~5% to 50%”).

1 requesting that the SEC “investigate whether Natera, Inc. has misled investors in violation of the
 2 Securities Act of 1934.”⁵⁶ The letter outlines the misleading nature of Natera’s NIPT results, and
 3 encourages the SEC to investigate the “company’s effort to persuade pregnant women and their doctors
 4 of the efficacy of NIPTs” to determine “whether Natera knowingly overstated the accuracy of its
 5 NIPT.”⁵⁷

6 62. Natera has been found to have engaged in deceitful business conduct. On March 14,
 7 2022, a jury in the District of Delaware awarded CareDx, a competing medical testing company, \$44.9
 8 million and found that Natera had engaged in false advertising and promotion regarding its kidney
 9 transplant assessment test, and had misled medical professionals, patients, and insurers.⁵⁸

10 63. In April 2022, the FDA issued a safety communication about NIPT (also called non-
 11 invasive prenatal screening or NIPS) tests, warning that “Genetic Non-Invasive Prenatal Screening Tests
 12 May Have False Results.”⁵⁹ The statement, directed to “patients and health care providers,” emphasizes
 13 that “[w]hile health care providers widely use NIPS tests, none have yet been authorized, cleared, or
 14 approved by the FDA” and “[t]he accuracy and performance of NIPS tests have not been evaluated by
 15 the FDA and these tests can give false results.”

16 64. The FDA safety communication notes that the FDA is aware of reports that “pregnant
 17 people have ended pregnancies based only on the results of NIPS tests,” and states that “[g]iven the
 18 increased use of these tests and concerns raised in recent media reports, the FDA is providing this
 19 information to educate patients and health care providers and to help reduce the inappropriate use of
 20 NIPS tests.”⁶⁰ The FDA safety communication also states that patients and health care providers alike
 21 “should be aware of the risks and limitations of using these screening tests,” and makes specific
 22 recommendations for patients and for health care providers to become better informed.

23 65. Further, the FDA safety communication notes “the risks related to the use of genetic
 24 prenatal screening and the potential harm if NIPS test results are not used and interpreted appropriately”

26 ⁵⁶ <https://www.documentcloud.org/documents/21179846-cfa-sec-natera-letter>.

27 ⁵⁷ *Id.*

28 ⁵⁸ See *Caredx, Inc. v. Natera, Inc.*, No. 19-cv-662-CFC-CJB (D. Del.), ECF No. 329.

⁵⁹ <https://www.fda.gov/medical-devices/safety-communications/genetic-non-invasive-prenatal-screening-tests-may-have-false-results-fda-safety-communication>.

⁶⁰ *Id.*

1 and “encourages test developers to provide accurate, clear, and complete information about the
 2 performance of their tests, how they should be used, and what the results may or may not mean.”⁶¹

3 66. Separately, in early 2022, a report by the Hastings Center (a nonpartisan, bioethics
 4 nonprofit) “analyze[d] all available English-language consumer-directed NIPT brochures,” and
 5 concluded that the communications “substantiate concerns about bias and inaccuracy in the promotion
 6 of these screening tests.”⁶² A brochure for Natera’s Panorama NIPT was one of the brochures
 7 analyzed.⁶³

8 67. The Hastings Report observes that “when these marketing materials are incomplete,
 9 unsubstantiated, inaccurate, misleading, or emotive, the consumer’s ability to make informed choices is
 10 compromised” and notes that “[p]oor-quality information poses the potential for harm from increased
 11 shock, distress, and confusion upon receipt of a high-chance result and may even lead to termination of
 12 an unaffected fetus if the possibility of a false-positive result is not clearly communicated.”⁶⁴

13 68. The report explains that “many of the promotional brochures had the potential to confuse
 14 would-be parents about what results actually show,” and why.⁶⁵ The report identifies several common
 15 aspects of NIPT company communications that are misleading to consumers.

16 69. **PPV rates:** “NIPT brochures should include sensitivity and PPV, rates of test failure,
 17 and reference to recent, high-quality data. Only 18 percent of the for-profit brochures offered sensitivity
 18 and PPV for each condition screened, and 50 percent discussed possible test failure.”⁶⁶

19 70. **Diagnostic vs. screening:** The Hastings Report cited three essential points to clearly
 20 communicating the difference between diagnostic testing and screening: 1) NIPT should be clearly
 21

22 ⁶¹ *Id.*

23 ⁶² Kelly Holloway, Nicole Simms, Robin Z. Hayeems & Fiona A. Miller, “The Market in Noninvasive
 24 Prenatal Tests and the Message to Consumers: Exploring Responsibility,” Hastings Center Report 52
 25 (2022) (“Hastings Report”) at 1, 3 (<https://www.documentcloud.org/documents/21411047-simms-ev-feb-9>).

26 ⁶³ Hastings Report Tables 1-5 and Methods, <https://www.thehastingscenter.org/wp-content/uploads/simms-supplementary-materials.pdf>.

27 ⁶⁴ Hastings Report at 2, 3.

28 ⁶⁵ C. Clark, *Prenatal Blood Test Info Often Misleads, Endangering Normal Pregnancies*, MedPage Today, <https://www.medpagetoday.com/special-reports/exclusives/97654>.

⁶⁶ Hastings Report at 5 (citing the Nuffield Council on Bioethics’ guidelines for NIPT company communications).

presented as a screening test, 2) it should not be represented as a replacement for invasive diagnostic testing, and 3) it should communicate that positive results must be confirmed through diagnostic testing.⁶⁷ The Hastings Report evaluated the NIPT brochures against the standards recognized by the Nuffield Council on Bioethics (the “Council”) and found that most companies offer misleading or conflicting information on this distinction, and “only 21% of for-profit companies’ NIPT brochures” had all three⁶⁸:

(a) First, “Many brochures were consistently unclear about distinguishing NIPT as a screening versus diagnostic test. Less than half (43 percent) of the for profit companies’ brochures clearly indicated that NIPT is not diagnostic.”⁶⁹

(b) Second, “Almost two-thirds (64 percent) of for-profit companies’ brochures represented NIPT as a replacement for or alternative to invasive testing.”⁷⁰

(c) Third, even though “[m]any brochures (64 percent) from for-profit companies did indicate that a positive result should be followed up with a diagnostic test,” the Hastings Report notes that conflicting information can “confuse consumers about the test’s capabilities. For example, a brochure could be clear about the fact that a test was a screening and not a diagnostic test, suggesting that a positive result on the screening test must be followed up with a diagnostic test—but could in other places represent NIPT as a replacement for invasive testing by presenting it as a way to ‘avoid unnecessary, risky invasive procedures such as amniocentesis and chorionic villus sampling.’”⁷¹

71. **Test implications:** The Council also “advises NIPT companies against suggesting that their tests will offer consumers reassurance or ‘peace of mind.’” Nevertheless, the Hastings Report found that 43 percent of for-profit companies’ brochures did present their tests this way.⁷²

72. **Claims of legitimacy despite a lack of regulatory oversight:** The Hastings Report further found that “[a]lthough statutory regulation evaluating NIPT for safety and efficacy before market

⁶⁷ *Id.* at 5 (citing the Nuffield Council on Bioethics' guidelines).

⁶⁸ *Id.* at 5-6.

⁶⁹ *Id.* at 5.

70 *Id.*

⁷¹ *Id.* at 6 (quoting an NIPT brochure).

72 *Id.*

1 access is not required, our concept-driven coding revealed consistent references to a number of entities
 2 involved in ‘regulating’ or guiding the manufacturing, use, or analysis of molecular diagnostics—
 3 particularly in the brochures from for-profit companies.”⁷³ “These references to external authorities were
 4 often made in relation to claims about test safety, accuracy, or quality” and “almost every brochure (93
 5 percent of the for-profit and 100 percent of the nonprofit brochures) stated that their NIPT was
 6 ‘accurate,’ ‘reliable,’ and/or ‘precise.’”⁷⁴

7 73. The report concludes that common reference “to external authorities such as the College
 8 of American Pathologists … could impart the impression that the test itself has been externally validated
 9 by such regulations and entities, even though that is not their function. Consumers who are attempting to
 10 make a decision about whether to use NIPTs are therefore presented with potentially misleading
 11 information.”⁷⁵

12 74. **Physicians as an authority:** In addition, the Hastings Report notes that consumers are
 13 commonly directed to the physician as a form of authority, despite the fact that “several studies indicate
 14 limitations in physicians’ understanding of NIPT’s function and results or a lack of confidence in their
 15 ability to communicate with patients about it.”⁷⁶ “This problem is compounded by the fact that most
 16 physicians offering advice to consumers are not specialists in the area of prenatal screening, and there is
 17 evidence that they rely, at least in part, on information produced by the companies in order to inform
 18 their patients.”⁷⁷

19
 20 ⁷³ *Id.*

21 ⁷⁴ *Id.* at 7.

22 ⁷⁵ *Id.*

23 ⁷⁶ *Id.* at 7-8 (citing L. Haymon *et al.*, “Clinical Implementation of Noninvasive Prenatal Testing
 24 among Maternal Fetal Medicine Specialists,” *Prenatal Diagnosis* 34, no. 5 (2014): 416-23; P. Swaney *et
 25 al.*, “Attitudes and Knowledge of Maternal-Fetal Medicine Fellows regarding Noninvasive Prenatal
 26 Testing,” *Journal of Genetic Counseling* 1, no. 25 (2016): 73-78; P. Benn *et al.*, “Obstetricians and
 27 Gynecologists’ Practice and Opinions of Expanded Carrier Testing and Noninvasive Prenatal Testing,”
 28 *Prenatal Diagnosis* 34, no. 2 (2014): 145-52.).

29 ⁷⁷ *Id.* at 8 (citing R. M. Farrell *et al.*, “The Use of Noninvasive Prenatal Testing in Obstetric Care:
 30 Educational Resources, Practice Patterns, and Barriers Reported by a National Sample of Clinicians,”
 31 *Prenatal Diagnosis* 36, no. 6 (2016): 499-506; L. Parham, M. Michie, and M. Allyse, “Expanding Use
 32 of cfDNA Screening in Pregnancy: Current and Emerging Ethical, Legal, and Social Issues,” *Current
 33 Genetic Medicine Reports* 1, no. 5 (2017): 44-53; ; A. C. Jelin *et al.*, “Obstetrician and Gynecologists’

1 75. Natera's brochures and other marketing material have many of the misleading
 2 characteristics identified by the Hastings Report.

3 (a) **PPV rates:** Natera did not advise consumers, including Plaintiffs, of the PPV rate
 4 of Panorama's tests. No information about PPVs is provided in Natera's current brochure.⁷⁸
 5 The current version of Natera's website touts the high "positive predictive value" or PPV of
 6 Panorama for Down syndrome but does not pair that figure with the very low PPV for rarer
 7 genetic conditions.



16 (b) **Diagnostic vs. screening:** Natera falsely implies that Panorama is a replacement
 17 for invasive diagnostic testing, advertising that its NIPT test does not pose the risks associated
 18 with diagnostic tests: "Panorama poses no risk to the baby compared to amniocentesis or
 19 chorionic villus sampling (CVS)."⁷⁹

20 (c) **Test implications:** Natera's Panorama brochure suggests that its test will give
 21 consumers peace of mind by offering the ability to "Discover more about your baby's health"
 22 and including a testimonial from a mother who says she is "now planning a birth at a regular
 23 maternity ward instead of closer to the children's hospital thanks to this painless test!"⁸⁰

26 Population-Based Screening Practices," *Journal of Maternal- Fetal & Neonatal Medicine* 29, no. 6
 27 (2016): 875-79; P. Swaney *et al.*, "Attitudes and Knowledge of Maternal-Fetal Medicine Fellows
 28 regarding Noninvasive Prenatal Testing," *Journal of Genetic Counseling* 1, no. 25 (2016): 73-78.

⁷⁸ <https://www.natera.com/resource-library/panorama/panorama-patient-brochure>.

⁷⁹ <https://www.natera.com/womens-health/panorama-nipt-prenatal-screening>.

⁸⁰ <https://www.natera.com/resource-library/panorama/panorama-patient-brochure>.

(d) **Claims of legitimacy despite a lack of regulatory oversight:** Natera advertises Panorama as “the most rigorously validated NIPT.”⁸¹ Natera’s website, for example, advertises Panorama as having been tested with “the largest prospective NIPT study” and makes vague, reassuring claims of outcomes of “~90% samples with genetic truth.”⁸²

(e) Just as the Hastings Report concludes that common reference “to external authorities such as the College of American Pathologists … could impart the impression that the test itself has been externally validated by such regulations and entities,”⁸³ Natera prominently cites the ACOG guidelines, which now recommend screening be offered in all pregnancies.⁸⁴

Recent ACOG guidelines support NIPT for all pregnancies¹

- Recommends NIPT as an option to be “discussed and offered to all patients early in pregnancy, regardless of maternal age or baseline risk.”
- Endorses cfDNA as the “most sensitive and specific screening test for the common fetal aneuploidies.”
- Highlights unique advantages of SNP-based NIPT, including triploidy detection and unique twins capabilities such as zygosity detection and individual fetal fraction measurements.

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ACOG PRACTICE BULLETIN
Clinical Management Guidelines for Obstetricians-Gynecologists

Number 226 | Published Online in May 2016 | ObGynNow.com

Screening for Fetal Chromosomal Abnormalities

ACOG Practice Bulletin—Obstetrics Committee and, Faculty for Maternal-Fetal Medicine, The Practice Bulletin Committee, and the Standing Committee on Ethics and Law. The Practice Bulletin Committee and the Standing Committee on Ethics and Law are committees of the American Congress of Obstetricians and Gynecologists. The Society for Maternal-Fetal Medicine, the American Society for Prenatal Pathology, and the Society for Women's Health Research also contributed to the development of this document. The Society for Maternal-Fetal Medicine, the American Society for Prenatal Pathology, and the Society for Women's Health Research are not members of the American Congress of Obstetricians and Gynecologists.

(f) **Physicians as an authority:** Just as in the brochures criticized in the Hastings Report, Natera directs consumers to consult with their doctors about the test. Also, as identified as problematic in that report, Natera markets Panorama to doctors with many of the same misleading claims of accuracy that doctors lack the expertise to evaluate. For example, in a brochure targeted at doctors, an image from which is reproduced below, Natera makes similar claims about the accuracy of its products, boasting that its tests are “validated with >99% sensitivity & specificity.” Natera urges, “[f]or more clinically relevant information, combine Panorama, with Vistara, the next innovation in NIPT technology.”⁸⁵

⁸¹ <https://www.natera.com/womens-health/panorama-nipt-prenatal-screening>.

82 Id.

83 *Id.*

⁸⁴ <https://www.natera.com/womens-health/panorama-nipt-prenatal-screening/average-risk/#pg-menu-abs>

⁸⁵ <https://www.natera.com/resource-library/panorama/panorama-vistara-physician-brochure>.



F. Consequences of a False Positive Test Result

76. A positive result on a prenatal test indicating that an unborn child has a genetic abnormality has far-reaching impacts on a pregnant patient.

77. Prospective parents fear that their pregnancy may not be viable, or that even if the child survives birth, it will be seriously impacted by a genetic disorder. The health implications of these conditions on the fetus, and the potential economic consequences of caring for a child born with genetic abnormalities, are so serious that many patients with a positive result consider whether to terminate the pregnancy. Some patients do terminate their pregnancies as a result of the positive test results.

78. One United Kingdom study in 2017 found that that 63% of U.K. women with high-risk NIPT results go on to terminate their pregnancies.⁸⁶

79. Compounding the difficult choice patients face about whether to continue the pregnancy, NIPT is usually performed early in a pregnancy before further diagnostic testing can definitively confirm whether the fetus truly is impacted. Even if diagnostic testing is available, it is highly invasive and there is a risk that the test itself will cause a miscarriage. And in some states where terminating a pregnancy is more tightly restricted, a parent with a positive test result may not have the option to wait for a diagnostic test before deciding whether to terminate.

80. In addition to the anguish for the potentially compromised health of their child, parents with positive test results also must contend with the prospect of expensive and stressful doctor's appointments with high-risk pregnancy specialists, often incurring increased costs for these extra visits and increased testing. As the *Times* reported, "Patients who receive a positive result are supposed to pursue follow-up testing, which often requires a drawing of amniotic fluid or a sample of placental

⁸⁶ M. Hill *et al.*, “Has Noninvasive Prenatal Testing Impacted Termination of Pregnancy and Live Birth Rates of Infants with Down Syndrome?,” *Prenatal Diagnosis* 37, no. 13 (2017): 1281-90.

1 tissue. Those tests can cost thousands of dollars, come with a small risk of miscarriage and can't be
 2 performed until later in pregnancy—in some states, past the point where abortions are legal.”⁸⁷

3 81. The *Times* also reported that “[t]he companies have known for years that the follow-up
 4 testing doesn’t always happen. A 2014 study found that 6 percent of patients who screened positive
 5 obtained an abortion without getting another test to confirm the result. That same year *The Boston*
 6 *Globe* quoted a doctor describing three terminations following unconfirmed positive results.”⁸⁸

7 82. False positives can and do lead to tragic results: “the follow-up testing revealed the fetus
 8 was healthy. But by the time the results came, the patient had already ended her pregnancy.”⁸⁹

9 **G. Plaintiffs’ Experiences with Natera’s Panorama Test**

10 **1. Lisa Cassinis**

11 83. Plaintiff Lisa Cassinis became pregnant in 2020. When she was in her first trimester, she
 12 purchased a Natera Panorama NIPT test. Before doing so, she reviewed Defendant’s Panorama NIPT
 13 test brochure.

14 84. Cassinis’s test results indicated that her unborn child was high risk for serious genetic
 15 conditions, including triploidy and trisomy 13.

16 85. Cassinis’s test results also gave details about each condition. They explained that
 17 “Almost all pregnancies with triploidy miscarry” and “The few babies that are born with triploidy
 18 usually do not live past a few days of life.” For trisomy 13, also called Patau syndrome, the results note
 19 that affected babies “often have serious birth defects and survivors experience severe intellectual
 20 disability.”

21 86. Natera did not disclose to Cassinis that, contrary to its claims that Panorama is highly
 22 accurate and reliable, the test is far less reliable and of little utility when screening for rare genetic
 23 conditions.

24 87. As a result of her Panorama test results, and despite concerns about the invasive nature of
 25 the test, Cassinis agreed to undergo CVS. The CVS test results indicated that her child did not have a
 26 genetic abnormality and the Panorama results were a false positive. Still, she underwent continued

27 87 <https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html>.

28 88 *Id.*

89 *Id.*

1 monitoring until the birth of her child. She saw a cardiac specialist, continued to see a maternal and
 2 fetal medicine specialist after that, and her child had a heart test when he was born. Her son was born
 3 healthy.

4 88. Cassinis suffered substantial distress as a result of the false positive Natera test result.
 5 She considered terminating and worried she might miscarry. Despite a normal CVS result, she was not
 6 certain that her child was healthy until he was born.

7 89. In addition to purchasing the Natera test itself, Cassinis also incurred expenses for
 8 significant follow up medical appointments and testing as a result of the Panorama results. She paid
 9 nearly \$200 for the Natera test itself, hundreds of dollars for genetic counseling, and thousands of
 10 dollars for the CVS test, related lab fees, and subsequent monitoring.

11 90. Nowhere in Natera's testing brochure, on its website, or in its marketing materials did
 12 Natera disclose the low PPV and high false positive rates associated with many of the conditions for
 13 which Panorama tests. Nor did Natera disclose in any marketing materials that, as a result of these
 14 deficiencies and others alleged herein, the Panorama test could not accurately or reliably determine
 15 whether Cassinis' baby had or was at risk of having a genetic abnormality.

16 91. Had Natera disclosed that the Panorama NIPT was neither accurate nor reliable to test for
 17 the majority of genetic conditions it purported to identify, Cassinis would not have purchased it, or
 18 would have paid significantly less for it. In addition to the other harm described herein, Cassinis
 19 suffered emotional distress, stress, and anxiety as a result of the unreliable Natera NIPT test she
 20 received.

21 **2. Sara Martinez**

22 92. Plaintiff Sara Martinez became pregnant in 2021. When she was in her first trimester, in
 23 approximately February 2022, she purchased a Natera Panorama NIPT test. Before doing so, she
 24 encountered descriptions of the product. She also reviewed Defendant's Panorama NIPT test brochure
 25 with her test results.

26 93. Martinez's test results indicated that her unborn child had an atypical finding on sex
 27 chromosomes, including potential Turner Syndrome, a serious genetic condition.

1 94. Natera did not disclose to Martinez that, contrary to its claims that Panorama is highly
 2 accurate and reliable, the test is far less reliable and of little utility when screening for many rare genetic
 3 conditions.

4 95. As a result of her Panorama test results, and despite concerns about the invasive nature of
 5 the test, Martinez agreed to undergo CVS. The CVS test results indicated that her child does not have a
 6 genetic abnormality and the Panorama results were a false positive. Her baby was born healthy.

7 96. Martinez suffered substantial distress as a result of the false positive Natera test result.
 8 She considered terminating, and worried that she might miscarry. Despite the CVS test result, she was
 9 not certain that her child was healthy until its birth.

10 97. In addition to purchasing the Natera test itself, Martinez incurred expenses for significant
 11 follow up medical appointments and testing as a result of the Panorama results. Martinez was charged
 12 approximately \$1,100 for these additional doctors' appointments and tests.

13 98. Nowhere in Natera's testing brochure, on its website, or in its marketing materials did
 14 Natera disclose the low PPV and high false positive rates associated with many of the conditions for
 15 which Panorama tests. Nor did Natera disclose in any marketing materials that, as a result of these
 16 deficiencies and others alleged herein, the Panorama test could not accurately or reliably determine
 17 whether Martinez's baby had or was at risk of having a genetic abnormality.

18 99. Had Natera disclosed that the Panorama NIPT was neither accurate nor reliable to test for
 19 the majority of genetic conditions it purported to identify, Martinez would not have purchased it, or
 20 would have paid significantly less for it. In addition to the other harm described herein, Martinez
 21 suffered emotional distress, stress, and anxiety as a result of the unreliable Natera NIPT test she
 22 received.

23 **3. Amanda Law**

24 100. Plaintiff Law became pregnant in 2018. In or about September 2018, when she was in
 25 her first trimester, Plaintiff Amanda Law purchased and took a Natera Panorama NIPT test while
 26 residing in Fort Lauderdale, Florida. Before doing so, Law reviewed Defendant's Panorama NIPT test
 27 brochures and marketing materials on Defendant's website while in Florida.

1 101. Law received her test results on September 24, 2018. Law's test results indicated that her
 2 unborn child was high risk for serious genetic conditions, including Triploidy and Trisomy 13.

3 102. Law's test results also gave details about each condition. The test results explained that
 4 "an increased incidence of pregnancy loss has [] been observed with this result." The test results went
 5 on to state that "[p]regnancies with triploidy . . . or trisomy 13 tend to have smaller than average
 6 placentas," that "[i]n general, babies with one of these conditions have serious birth defects and
 7 significantly shortened lifespans," and that "[i]t is rare for a baby with triploidy to be liveborn."

8 103. Natera did not disclose to Law that, contrary to its claims that Panorama is highly
 9 accurate and reliable, the test is far less reliable and of little utility when screening for many rare genetic
 10 conditions.

11 104. As a result of her Panorama test results, Law underwent subsequent monitoring by a
 12 high-risk specialist. That monitoring indicated that her child did not have a genetic abnormality and the
 13 Panorama results were a false positive.

14 105. Law paid for her Panorama NIPT test out-of-pocket because it was not covered by her
 15 insurance. In addition to purchasing the Natera test itself, Law also incurred expenses for significant
 16 follow up medical appointments and testing as a result of the Panorama results.

17 106. Law suffered substantial distress as a result of the false positive Natera test result and felt
 18 immense pressure to terminate her pregnancy. Law chose to continue with her pregnancy and ultimately
 19 gave birth to a healthy baby girl who did not suffer from any chromosomal abnormalities.

20 107. Nowhere in Natera's testing brochure, on its website, or in its marketing materials did
 21 Natera disclose the low PPV and high false positive rates associated with many of the conditions for
 22 which Panorama tests. Nor did Natera disclose in any marketing materials that, as a result of these
 23 deficiencies and others alleged herein, the Panorama test could not accurately or reliably determine
 24 whether Law's baby had or was at risk of having a genetic abnormality.

25 108. Had Natera disclosed that the Panorama NIPT was neither accurate nor reliable to test for
 26 the majority of genetic conditions it purported to identify, Law would not have purchased it, or would
 27 have paid significantly less for it. In addition to the other harm described herein, Law suffered
 28 emotional distress, stress, and anxiety as a result of the unreliable Natera NIPT test she received.

4. Lillian Delaurie

109. Plaintiff Lilian Delaurie became pregnant in 2021. When she was in her first trimester, in approximately February 2022, she purchased a Natera Panorama NIPT test. Before doing so, she reviewed Defendant's Panorama NIPT test brochure.

110. Delaurie's test results indicated that her unborn child was high risk for serious genetic conditions, including triploidy and trisomy 13.

111. Delaurie's test results also gave details about each condition. They explained that "Almost all pregnancies with triploidy miscarry" and "The few babies that are born with triploidy usually do not live past a few days of life." For trisomy 13, the results note that affected babies "often have serious birth defects and survivors experience severe intellectual disability."

112. Natera did not disclose to Delaurie that, contrary to its claims that Panorama is highly accurate and reliable, the test is far less reliable and of little utility when screening for many rare genetic conditions.

113. Delaurie purchased another Panorama test, but the second set of results also showed high risk for the same conditions.

114. Delaurie spoke with one of Natera's genetic counselors on or about March 7, 2022, who told her that 99% of these tests are accurate.

115. As a result of her Panorama test results, and despite concerns about the invasive nature of the test, Delaurie agreed to undergo amniocentesis. The amniocentesis test results indicated that her baby did not have a genetic abnormality and the Panorama results were a false positive. Her baby was born healthy.

116. Delaurie suffered substantial distress as a result of the false positive Natera test result. She considered terminating, and worried that she might miscarry. Despite the amniocentesis test result, she was not certain that her baby would be healthy until it was born.

117. In addition to purchasing the Natera test itself, Delaurie also incurred expenses for significant follow up medical appointments and testing as a result of the Panorama results.

118. Nowhere in Natera's testing brochure, on its website, or in its marketing materials did Natera disclose the low PPV and high false positive rates associated with many of the conditions for

1 which Panorama tests. Nor did Natera disclose in any marketing materials that, as a result of these
 2 deficiencies and others alleged herein, the Panorama test could not accurately or reliably determine
 3 whether Delaurie's baby had or was at risk of having a genetic abnormality.

4 119. Had Natera disclosed that the Panorama NIPT was neither accurate nor reliable to test for
 5 the majority of genetic conditions it purported to identify, Delaurie would not have purchased it, or
 6 would have paid significantly less for it. In addition to the other harm described herein, Delaurie
 7 suffered emotional distress, stress, and anxiety as a result of the unreliable Natera NIPT test she
 8 received.

9 **5. Laura Ashley Heryla**

10 120. Plaintiff Laura Ashley Heryla became pregnant in 2021. When she was in her first
 11 trimester, she purchased a Natera Panorama NIPT test. Before doing so, she reviewed Defendant's
 12 Panorama NIPT test brochure.

13 121. Heryla's test results indicated that her unborn child was high risk for serious genetic
 14 conditions, including triploidy and trisomy 13.

15 122. Heryla's test results also gave details about each condition. They explained that "Almost
 16 all pregnancies with triploidy miscarry" and "The few babies that are born with triploidy usually do not
 17 live past a few days of life." For trisomy 13, the results note that affected babies "often have serious
 18 birth defects and survivors experience severe intellectual disability."

19 123. Natera did not disclose to Heryla that, contrary to its claims that Panorama is highly
 20 accurate and reliable, the test is far less reliable and of little utility when screening for many rare genetic
 21 conditions.

22 124. As a result of her Panorama test results, Heryla sought treatment from a high-risk doctor.
 23 Heryla underwent a second NIPT test, which indicated that her child likely did not have a genetic
 24 abnormality and the first Panorama results were a false positive. Still, she underwent continued
 25 monitoring with the high-risk doctor until the birth of her child. Her daughter was born healthy.

26 125. Heryla suffered substantial distress as a result of the false positive Natera test result. She
 27 considered terminating if results were confirmed, and worried that she might miscarry. Despite the
 28

1 second NIPT test result, she was not certain that her child was healthy until she was born and felt fear
 2 throughout the entire pregnancy.

3 126. In addition to purchasing the Natera test itself, Heryla also incurred expenses for
 4 significant follow up medical appointments and testing as a result of the Panorama results. She paid
 5 over \$700 out of pocket for the Natera tests and over \$4,500 out of pocket for appointments with a high
 6 risk doctor and associated tests and fees.

7 127. Nowhere in Natera's testing brochure, on its website, or in its marketing materials did
 8 Natera disclose the low PPV and high false positive rates associated with many of the conditions for
 9 which Panorama tests. Nor did Natera disclose in any marketing materials that, as a result of these
 10 deficiencies and others alleged herein, the Panorama test could not accurately or reliably determine
 11 whether Heryla's baby had or was at risk of having a genetic abnormality.

12 128. Had Natera disclosed that the Panorama NIPT was neither accurate nor reliable to test for
 13 the majority of genetic conditions it purported to identify, Heryla would not have purchased it, or would
 14 have paid significantly less for it. In addition to the other harm described herein, Heryla suffered
 15 emotional distress, stress, and anxiety as a result of the unreliable Natera NIPT test she received.

16 6. **Yelena Kreynstein**

17 129. Plaintiff Kreynstein became pregnant in 2019. During her pregnancy, Plaintiff Yelena
 18 Kreynstein's baby was diagnosed with a congenital heart defect that is sometimes associated with
 19 DiGeorge syndrome. As a result, in April 2020, Plaintiff Kreynstein purchased and took a Natera
 20 Panorama NIPT test in New Jersey to specifically test for DiGeorge syndrome. Before doing so,
 21 Kreynstein reviewed Defendant's Panorama NIPT test brochures and marketing materials.

22 130. Kreynstein's test results indicated that her unborn child was high risk for DiGeorge
 23 syndrome, which can cause many health issues, including heart defects, developmental delays, kidney
 24 abnormalities, and cleft palates.

25 131. Natera did not disclose to Kreynstein that, contrary to its claims that Panorama is highly
 26 accurate and reliable, the test is far less reliable and of little utility when screening for many rare genetic
 27 conditions.

1 132. Kreynstein paid approximately \$200 out-of-pocket for the test. In addition to purchasing
 2 the Natera test itself, Kreynstein also incurred expenses for significant follow up medical appointments
 3 and testing as a result of the Panorama results.

4 133. Kreynstein suffered substantial distress as a result of the false positive Natera test result.
 5 As a result of her Panorama test results, Plaintiff Kreynstein underwent amniocentesis, which indicated
 6 that her child did not have DiGeorge syndrome and the Panorama results were a false positive.
 7 Kreynstein ultimately continued with her pregnancy, and gave birth to a baby girl who did not suffer
 8 from any chromosomal abnormalities but who has since had surgery to repair her heart defect.

9 134. Nowhere in Natera's testing brochure, on its website, or in its marketing materials did
 10 Natera disclose the low PPV and high false positive rates associated with many of the conditions for
 11 which Panorama tests. Nor did Natera disclose in any marketing materials that, as a result of these
 12 deficiencies and others alleged herein, the Panorama test could not accurately or reliably determine
 13 whether Kreynstein's baby had or was at risk of having a genetic abnormality.

14 135. Had Natera disclosed that the Panorama NIPT was neither accurate nor reliable to test
 15 for the majority of genetic conditions it purported to identify, Kreynstein would not have purchased it, or
 16 would have paid significantly less for it. In addition to the other harm described herein, Kreynstein
 17 suffered emotional distress, stress, and anxiety as a result of the unreliable Natera NIPT test she
 18 received.

19 **7. Chelsey Stephens**

20 136. Plaintiff Stephens became pregnant in 2022. In or about December 2022, when she was
 21 in her first trimester, Stephens paid for and took a Natera Panorama NIPT test while residing in
 22 Brooklyn, New York. Prior to paying for the Panorama NIPT test, Stephens encountered materials
 23 prepared by Natera.

24 137. Stephens received her test results on December 16, 2022. Stephens' test results indicated
 25 that her unborn child was at high risk for Monosomy X, which can cause many health issues, including
 26 infertility, heart defects, diabetes, low thyroid hormone, and a high risk that the child would not be born
 27 alive.

1 138. Natera did not disclose to Stephens that, contrary to its claims that Panorama is highly
 2 accurate and reliable, the test is far less reliable and of little utility when screening for many rare genetic
 3 conditions.

4 139. As a result of her Panorama test results, Stephens underwent subsequent monitoring by a
 5 high-risk specialist. That monitoring included the purchase of further NIPT tests—which also returned
 6 false positive results—and an invasive amniocentesis procedure. The amniocentesis procedure showed
 7 that her child did not have a genetic abnormality and the Panorama NIPT test result was a false positive.

8 140. Stephens paid approximately \$75 out-of-pocket for the test. In addition to purchasing the
 9 Natera test itself, Stephens also incurred expenses for significant follow-up medical appointments and
 10 testing as a result of the Panorama results.

11 141. Stephens suffered substantial distress as a result of the false positive Natera test result and
 12 felt immense pressure to terminate her pregnancy. Stephens chose to continue with her pregnancy,
 13 which her amniocentesis results ultimately found was normal.

14 142. Nowhere in Natera’s testing brochure, on its website, or in its marketing materials did
 15 Natera disclose the low PPV and high false positive rates associated with many of the conditions for
 16 which Panorama tests. Nor did Natera disclose in any marketing materials that, as a result of these
 17 deficiencies and others alleged herein, the Panorama test could not accurately or reliably determine
 18 whether Stephen’s baby had or was at risk of having a genetic abnormality.

19 143. Had Natera disclosed that the Panorama NIPT was neither accurate nor reliable to test for
 20 the majority of genetic conditions it purported to identify, Stephens would not have purchased it, or would
 21 have paid significantly less for it. In addition to the other harm described herein, Stephens suffered
 22 emotional distress, stress, and anxiety as a result of the unreliable Natera NIPT test she received.

23 **8. Amanda Davis**

24 144. Plaintiff Amanda Davis became pregnant in 2020. When she was in her first trimester,
 25 she purchased a Natera Panorama NIPT test. Before doing so, she reviewed Defendant’s Panorama
 26 NIPT test brochure.

145. Davis's test results showed an "atypical finding," noting there was a "[s]uspected finding outside the scope of the test, which may include, but is not limited to, fetal mosaicism, fetal chromosome abnormality [or] maternal chromosome abnormality."

146. Natera did not disclose to Davis that, contrary to its claims that Panorama is highly accurate and reliable, the test is far less reliable and is of little utility when screening for rare genetic conditions.

147. As a result of her Panorama test results, Davis underwent subsequent monitoring by a high-risk specialist. That monitoring indicated that her child did not have a genetic abnormality and the Panorama results were a false positive. Her son was born healthy.

148. Davis suffered substantial distress as a result of the false positive Natera test result. She considered terminating, and worried that she might miscarry. Despite that subsequent monitoring showed no abnormalities, she was not certain that her child was healthy until he was born.

149. In addition to purchasing the Natera test itself, Davis also incurred expenses for significant follow up medical appointments and testing as a result of the Panorama results. She paid approximately \$100 out of pocket for the Natera test and approximately three thousand dollars out of pocket for additional doctors' appointments.

150. Nowhere in Natera's testing brochure, on its website, or in its marketing materials did Natera disclose the low PPV and high false positive rates associated with many of the conditions for which Panorama tests. Nor did Natera disclose in any marketing materials that, as a result of these deficiencies and others alleged herein, the Panorama test could not accurately or reliably determine whether Davis's baby had or was at risk of having a genetic abnormality.

151. Had Natera disclosed that the Panorama NIPT was neither accurate nor reliable to test for the majority of genetic conditions it purported to identify, Davis would not have purchased it, or would have paid significantly less for it. In addition to the other harm described herein, Davis suffered emotional distress, stress, and anxiety as a result of the unreliable Natera NIPT test she received.

* * *

152. Plaintiffs each are either currently pregnant, anticipate potentially becoming pregnant in the future, or both. Each Plaintiff, while pregnant, prefers to have as much information as possible as

1 possible concerning their potential child, and so each has a desire to use Natera's NIPT Panorama test in
 2 the future. Natera, however, continues to provide misleading and incomplete information concerning
 3 the accuracy and reliability of its Panorama test. Given their experiences, Plaintiffs do not trust Natera's
 4 representations about its tests. As a result, although Plaintiffs would like to purchase Natera's Panorama
 5 test again, they will not do so unless Natera takes sufficient steps to effectively ensure the accuracy of its
 6 representations about the test.

7 **VI. CLASS ACTION ALLEGATIONS**

8 153. Plaintiffs bring this suit as a class action on behalf of themselves and all other persons
 9 similarly situated, pursuant to Federal Rules of Civil Procedure 23(a), (b)(2), and (b)(3), as
 10 representative of all persons who purchased for personal use Natera's NIPT testing services within the
 11 United States (the "Class").

12 154. In addition, Plaintiffs Cassinis and Martinez sue on behalf of a subclass consisting of all
 13 persons who purchased for personal use Natera's NIPT testing services within California (the
 14 "California Subclass"); Plaintiff Davis sues on behalf of a subclass consisting of all persons who
 15 purchased for personal use Natera's NIPT testing services within Ohio (the "Ohio Subclass"); Plaintiff
 16 Heryla sues on behalf of a subclass consisting of all persons who purchased for personal use Natera's
 17 NIPT testing services within Maryland (the "Maryland Subclass"); Plaintiff Delaurie sues on behalf of a
 18 subclass consisting of all persons who purchased for personal use Natera's NIPT testing services within
 19 Illinois (the "Illinois Subclass"); Plaintiff Kreynstein sues on behalf of a subclass consisting of all
 20 persons who purchased for personal use Natera's NIPT testing services within New Jersey (the "New
 21 Jersey Subclass"); Plaintiff Law sues on behalf of a subclass consisting of all persons who purchased for
 22 personal use Natera's NIPT testing services within Florida (the "Florida Subclass"); and Plaintiff
 23 Stephens sues on behalf of a subclass consisting of all persons who purchased for personal use Natera's
 24 NIPT testing services within New York (the "New York Subclass").

25 155. The Class and the state Subclasses are referred to collectively herein as the "Class."
 26 Excluded from the Class are Defendant, its affiliates, employees, officers and directors, and the Judge(s)
 27 assigned to this case. Plaintiffs reserve the right to modify, change or expand the Class and Subclass
 28 definitions based on discovery and further investigation.

1 156. This action is brought as a class action and may properly be so maintained pursuant to the
 2 provisions of Rule 23 of the Federal Rules of Civil Procedure.

3 157. **Numerosity** – The members of the Class are so numerous that their individual joinder is
 4 impracticable. While the exact number of individual Class members is unknown at this time, Plaintiffs
 5 believe the information is in the possession of Natera, and that Class membership is determinable by
 6 objective criteria using Defendant’s own records.

7 158. **Existence and Predominance of Common Question of Fact and Law** – There are
 8 questions of law and fact common to the Class. These questions predominate over any questions
 9 affecting only individual class members and include, but are not limited to:

- 10 (a) Whether Defendant’s NIPT test is accurate and reliable;
- 11 (b) Whether the marketing, advertising, packaging, labeling, and other
 12 promotional materials for Panorama are deceptive;
- 13 (c) Whether Defendant has a duty to disclose the complete truth regarding the
 14 accuracy and reliability of its NIPT test;
- 15 (d) Whether Defendant concealed material information about the accuracy and
 16 reliability of its NIPT test results;
- 17 (e) Whether Defendant’s conduct violates the laws set forth in the causes of
 18 action;
- 19 (f) Whether Plaintiffs and the Class have been harmed as a result of
 20 Defendant’s conduct alleged herein;
- 21 (g) Whether Defendant has been unjustly enriched as a result of the conduct
 22 alleged herein; and
- 23 (h) Whether Plaintiffs and the Class are entitled to declaratory and injunctive
 24 relief.

25 159. **Typicality** – Plaintiffs’ claims are typical of the claims of the Class. Plaintiffs and the
 26 Class were subjected to the same common pattern of conduct by Defendant, and Plaintiffs, like the other
 27 members of the Class, sustained damages arising from Defendant’s violations of the law, as alleged
 herein.

160. **Adequacy** – Plaintiffs will fairly and adequately represent and protect the interests of the
 2 Class and has retained competent counsel who are highly experienced in complex class actions and who
 3 intend to vigorously prosecute this action. There are no material conflicts between Plaintiffs and the
 4 members of the Class.

161. **Superiority** – A class action is superior to other available means for the fair and efficient
 2 adjudication of this dispute. The injury suffered by each individual Class member is relatively small in
 3 comparison to the burden and expense of prosecuting these claims individually. Individualized
 4 litigation also would risk inconsistent or contradictory judgments and increase the delay and expense to
 5 all parties and the courts. By contrast, a class action presents far fewer management difficulties and
 6 provides the benefits of single adjudication, economies of scale, and comprehensive supervision by a
 7 single court.

162. Class Certification is also appropriate under Rules 23(b)(1), (b)(2), and/or (c)(4) because:

- 163. • The prosecution of separate actions by individual members of the Class would create a
 14 risk of inconsistent or varying adjudications establishing incompatible standards of
 15 conduct for Natera.
- 164. • The prosecution of separate actions by individual Class members would create a risk of
 17 adjudications that would, as a practical matter, be dispositive of the interests of other
 18 Class members not parties to the adjudications, or would substantially impair or impede
 19 their ability to protect their interests.
- 20 • Natera has acted or refused to act on grounds generally applicable to the Class, making
 21 injunctive and corresponding declarative relief appropriate with respect to the Class as a
 22 whole; and
- 23 • The claims of class members are comprised of common issues whose resolution in a class
 24 trial would materially advance this litigation.

25 **VII. CAUSES OF ACTION**

26 **COUNT I**

27 **Violation of the Unfair Competition Law (Cal. Bus. & Prof. Code § 17200, *et seq.*) (“UCL”)**

28 163. Plaintiffs incorporate and reallege the foregoing allegations of fact.

1 164. Plaintiffs Cassinis and Martinez bring this claim on behalf of the California Subclass.

2 165. Natera is a “person” under Cal. Bus. & Prof. Code § 17201.

3 166. The UCL proscribes acts of unfair competition, including “any unlawful, unfair or
4 fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising.” Cal. Bus. &
5 Prof. Code § 17200.

6 **Unlawful Conduct**

7 167. Natera’s conduct is unlawful and therefore violates the UCL because, as set forth herein,
8 it violates the Song-Beverly Consumer Warranty Act.

9 **Unfair Conduct**

10 168. Natera’s conduct is unfair because it violates California’s public policies regarding
11 consumer protection and health and safety.

12 169. Natera violated the Song-Beverly Consumer Warranty Act, as set forth herein, by selling
13 a product that was unreliable and unmerchantable. For many genetic conditions, the Panorama prenatal
14 test produces a false positive more often than it produces a true positive. The test is therefore unfit for
15 the primary purpose for which prenatal tests are used—accurately determining the risk of serious genetic
16 conditions.

17 170. Natera’s reporting of inaccurate and unreliable results also contravenes the policy of
18 California Health and Safety Code §§ 125050-55, which requires the state to administer a program “for
19 the prenatal testing for genetic disorders and birth defects[.]” This program includes maternal blood
20 testing for genetic disorders and requires the state to “[d]evelop an education program designed to
21 educate physicians and surgeons and the public concerning the uses of prenatal testing[.]” Cal. Health &
22 Safety Code §§ 125050-55. Natera’s reporting of inaccurate and unreliable results to pregnant women is
23 at odds with the Legislature’s intent that physicians and their patients understand the benefits and use of
24 prenatal testing.

25 171. Moreover, by selling inaccurate and unreliable NIPT tests to women in a sensitive life
26 phase, Natera acted unscrupulously.

27 172. Natera’s conduct set forth in this Complaint gave it a competitive advantage but caused
28 California consumers substantial injury. Plaintiffs Cassinis and Martinez paid for and underwent

additional unnecessary, invasive tests that involved a risk of miscarriage. They paid for and underwent substantial medical monitoring and attended unnecessary appointments with specialists and genetic counselors.

173. The gravity of the harm resulting from Natera's unfair conduct far outweighs any potential utility. Natera's Panorama test is of little use for identifying the presence of rare genetic conditions. For many genetic disorders, the Panorama test produces more false positives than true positives. Consumers reasonably expect a NIPT test to accurately and reliably predict a genetic abnormality at a rate significantly higher than 2-5%.

174. Natera's sharp practice of selling unreliable, often inaccurate NIPT tests harms the public at large and is part of a common and uniform course of wrongful conduct.

175. There are reasonably available alternatives that would further Natera's legitimate business interests. Natera could have produced more reliable prenatal tests or provided accurate warnings of the propensity of NIPT testing to yield false positives for serious genetic syndromes.

176. The harm from Natera's unfair conduct was not reasonably avoidable by consumers. Plaintiffs Cassinis and Martinez and California Subclass members, as well as their treating physicians, did not know, and had no reasonable means of discovering, that Natera's Panorama test produces a high rate of false positives and is unreliable.

177. Plaintiff Cassinis and Martinez and California Subclass members are therefore entitled to an injunction, restitution, and reasonable attorneys' fees including under California Code of Civil Procedure section 1021.5.

COUNT II

Violation of the Song-Beverly Consumer Warranty Act (Cal. Civ. Code, § 1790, *et seq.*)

178. Plaintiffs incorporate and reallege the foregoing allegations of fact.

179. Plaintiffs Cassinis and Martinez bring this claim on behalf of themselves and the California Subclass.

180. Plaintiffs Cassinis and Martinez are “buyers” within the meaning of California Civil Code section § 1791(b). Each purchased a Natera Panorama prenatal test in California.

1 181. Natera is a manufacturer within the meaning of California Civil Code section 1791(j).
 2 Natera is responsible for producing Natera prenatal tests; it directed and was involved in all stages of the
 3 production and manufacturing processes.

4 182. Natera's Panorama prenatal test is a "consumer good[]" within the meaning of California
 5 Civil Code section 1791(a).

6 183. Natera impliedly warranted to Plaintiffs Cassinis and Martinez that the Panorama
 7 prenatal test each purchased was "merchantable" under California Civil Code sections 1791.1(a) and
 8 1792.

9 184. Natera breached the implied warranty of merchantability by producing, manufacturing,
 10 and selling Panorama prenatal tests that were not of merchantable quality. The Panorama prenatal test is
 11 unreliable, producing a false positive the majority of the time for many genetic conditions. The test is
 12 therefore unfit for the ordinary purposes for which prenatal tests are used—accurately detecting risk for
 13 serious genetic conditions.

14 185. The unreliability in Natera's Panorama prenatal tests is latent. Test results are reported as
 15 accurate, but the unreliability existed in the product at the time of sale. Plaintiffs and California
 16 Subclass members had no reasonable means of discovering that Natera's NIPT tests are unreliable.
 17 Accordingly, any subsequent discovery of the reliability beyond that time does not bar an implied
 18 warranty claim under the Song-Beverly Act.

19 186. Any attempt by Natera to disclaim its implied warranty obligations under the Song-
 20 Beverly Act is ineffective due to its failure to adhere to California Civil Code sections 1792.3 and
 21 1792.4. Those sections provide that, in order to validly disclaim the implied warranty of
 22 merchantability, a manufacturer must "in simple and concise language" state: "(1) The goods are being
 23 sold on an 'as is' or 'with all faults' basis. (2) The entire risk as to the quality and performance of the
 24 goods is with the buyer. (3) Should the goods prove defective following their purchase, the buyer and
 25 not the manufacturer, distributor, or retailer assumes the entire cost of all necessary servicing or repair."
 26 Therefore any attempted warranty disclaimer does not conform to sections 1792.3 and 1792.4.

187. As a direct and proximate cause of Natera's breaches of the Song-Beverly Consumer
Warranty Act, Plaintiffs Cassinis, Martinez, and California Subclass members have been damaged in an
amount to be proven at trial.

188. Plaintiffs Cassinis and Martinez seek costs and expenses, including reasonable attorneys' fees, under California Civil Code section 1794.

COUNT III

Violation of the Maryland Consumer Protection Act (Md. Code Ann. Com. Law § 13-101, *et seq.*)

189. Plaintiffs incorporate and reallege the foregoing allegations of fact.

190. Plaintiff Heryla brings this claim on behalf of herself and the Maryland Subclass.

191. Plaintiff Heryla and Maryland Subclass members are “consumers” within the meaning of Md. Code Com. Law § 13-101(c)(1).

192. Plaintiff Heryla, Maryland Subclass members, and Natera are “persons” within the meaning of Md. Code Com. Law § 13-101(h).

193. Natera's NIPT tests are “consumer goods” within the meaning of Md. Code Com. Law § 13-101(d)(2).

194. Maryland law prohibits unfair, abusive, or deceptive trade practices including any “[f]alse, falsely disparaging, or misleading oral or written statement, visual description, or other representation of any kind which has the capacity, tendency, or effect of deceiving or misleading consumers.” Md. Code Com. Law § 13-301(1). Maryland law also prohibits representations that a consumer good has characteristics, use, benefit, or quantity which it does not have; the omission of a material fact if it deceives or tends to deceive; and the misrepresentation, knowing concealment, or omission of material fact with the intent that a consumer rely on the same in connection with the promotion or sale of a consumer good. *Id.* at 13-301(2), (3), (9).

195. Natera engaged in unfair acts and practices by developing and selling Panorama NIPT tests that were inaccurate and unreliable to test for a variety of genetic abnormalities. Natera derived a substantial financial benefit from its sale of these tests.

196. Natera engaged in deceptive, unfair and abusive practices by omitting material information for purposes of inducing consumers to purchase and submit to Natera for prenatal testing

1 services. Natera actively suppressed and failed to disclose material facts concerning the accuracy and
 2 reliability of its NIPT test, including:

- 3 (a) knowingly and intentionally concealing from Plaintiffs, Class members, and their
 4 physicians the fact that the Panorama test is inaccurate for many rare disorders, is highly
 5 susceptible to false positives, and cannot be relied on to make critical decisions during a
 6 pregnancy;
- 7 (b) failing to disclose that the PPV for rare but serious conditions such as Trisomy 13,
 8 Monosomy X, and DiGeorge Syndrome is much lower, sometimes as low as 2-5%;
- 9 (c) failing to reveal that for rare disorders such as DiGeorge syndrome, there is actually an
 10 80% or greater chance a positive result is wrong; and
- 11 (d) failing to disclose the high risk of false positives.

12 197. Natera owed Plaintiff Heryla and Maryland Subclass members a duty to disclose these
 13 facts because Natera had exclusive and superior knowledge of them; because they would be material to
 14 reasonable consumers; and because Natera intended for consumers to rely on the omissions in question.

15 198. Natera could have readily disclosed the truth regarding its Panorama NIPT tests to
 16 Plaintiff and Maryland Subclass members through various sources, including its website, product
 17 brochures and marketing materials, and through Plaintiff Heryla's and Maryland Subclass members'
 18 physicians and health care providers.

19 199. Defendant's omissions were pervasive and deceived Plaintiff Heryla and Maryland
 20 Subclass members, and have a tendency to deceive the general public regarding the reliability and value
 21 of Panorama NIPT tests. The omissions by Natera alleged herein were material in that a reasonable
 22 person would attach importance to them and would be induced to act on the information in making
 23 decisions. Reasonable consumers would have been expected to have relied on the omissions.

24 200. Natera possessed superior knowledge regarding the accuracy and reliability of its NIPT
 25 tests, which was not reasonably discoverable by Plaintiffs, Maryland Subclass members, or their treating
 26 physicians. Plaintiff Heryla and Maryland Subclass members reasonably relied on Natera's omissions to
 27 their detriment, including by paying money for testing they would not have utilized had they been
 28 apprised of the true facts.

201. Defendant knew or should have known that its omissions were false and misleading, and intended for consumers to rely on such omissions.

202. Plaintiff Heryla and Maryland Subclass members suffered ascertainable loss as a direct and proximate result of Natera's unfair, abusive, and deceptive trade practices. Had Plaintiff Heryla and Maryland Subclass members known the truth regarding Natera's NIPT test, they would not have purchased a test, or would have paid significantly less for one. Among other injuries, Plaintiff Heryla and Maryland Subclass members overpaid for their NIPT tests and did not receive the value they bargained for.

203. Accordingly, Plaintiff Heryla and Maryland Subclass members are entitled to actual compensatory damages and reasonable attorneys' fees pursuant to Md. Code Com. Law § 13-408.

COUNT IV

Violation of the Illinois Consumer Fraud and Deceptive Business Practices Act (815 Ill. Comp. Stat. § 505/1, *et seq.*)

204. Plaintiffs incorporate and reallege the foregoing allegations of fact.

205. Plaintiff Delaurie brings this claim on behalf of herself and the Illinois Subclass.

206. Plaintiff Delaurie and Illinois Subclass members are “consumers” within the meaning of 815 Ill. Comp. Stat. § 505/1(e).

207. Plaintiff Delaurie, Illinois Subclass members, and Natera are “persons” within the meaning of 815 Ill. Comp. Stat. § 505/1(c).

208. Natera engages in “trade” or “commerce” within the meaning of 815 Ill. Comp. Stat. § 505/1(f).

209. Natera engages in the “sale” of “merchandise” as those terms are defined by 815 Ill. Comp. Stat. § 505/1(b) and (d).

210. Illinois law prohibits “[u]nfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception, fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact . . . in the conduct of any trade or commerce.” 815 Ill. Comp. Stat. § 505/2.

1 211. Natera engaged in unfair acts and practices by developing and selling Panorama NIPT
 2 tests that were inaccurate and unreliable to test for a variety of genetic abnormalities. Natera derived a
 3 substantial financial benefit from its sale of these tests.

4 212. Natera engaged in deceptive practices by omitting material information for purposes of
 5 inducing consumers to purchase and submit to Natera for prenatal testing services. Natera actively
 6 suppressed and failed to disclose material facts concerning the accuracy and reliability of its NIPT test,
 7 including:

- 8 (a) knowingly and intentionally concealing from Plaintiffs, Class members, and their
 9 physicians the fact that the Panorama test is widely inaccurate for many rare
 10 disorders, is highly susceptible to false positives, and cannot be relied on to make
 11 critical decisions during a pregnancy;
- 12 (b) failing to disclose that the PPV for rare but serious conditions such as Trisomy 13,
 13 Monosomy X, and DiGeorge Syndrome is much lower, sometimes as low as 2-
 14 5%;
- 15 (c) failing to reveal that for rare disorders such as DiGeorge syndrome, there is
 16 actually an 80% or greater chance a positive result is wrong; and
- 17 (d) failing to disclose the high risk of false positives.

18 213. Natera omitted such material facts for purposes of inducing consumers to purchase and
 19 submit to Natera for prenatal testing services. Natera knowingly sold inaccurate and unreliable NIPT
 20 tests, made misleading and deceptive claims regarding its NIPT tests, and failed to disclose the complete
 21 truth regarding its NIPT tests to consumers and their treating physicians.

22 214. Natera's conduct was fraudulent and deceptive because the omissions and incomplete
 23 disclosures of fact had the capacity, tendency, and effect of deceiving or misleading reasonable
 24 consumers and did, in fact, deceive and mislead reasonable consumers including the Plaintiffs.

25 215. Reasonable consumers, including Plaintiff Delaurie and the Illinois Subclass, would have
 26 found it material to their purchasing decisions that Natera's products (i) were not reasonably accurate or
 27 reliable, (ii) have a low positive predictive value, (iii) were not diagnostic tests, and (iv) cannot replace
 28

1 diagnostic tests. Knowledge of these facts would have been a substantial factor in Plaintiff Delaurie's
 2 and Illinois Subclass members' decisions to purchase Natera's products.

3 216. Natera owed Plaintiff Delaurie and Illinois Subclass members a duty to disclose these
 4 facts because Natera had exclusive and superior knowledge of them; because they would be material to
 5 reasonable consumers; and because Natera intended for consumers to rely on the omissions in question.

6 217. Natera could have readily disclosed the entire truth regarding its Panorama NIPT tests to
 7 Plaintiff Delaurie and Illinois Subclass members through various sources, including its website, product
 8 brochures and marketing materials, and through Plaintiff Delaurie and Illinois Subclass members'
 9 physicians and health care providers.

10 218. Defendant's omissions and incomplete disclosures were pervasive and deceived Plaintiff
 11 Delaurie and Illinois Subclass members, and have a tendency to deceive the general public regarding the
 12 reliability and value of the Panorama NIPT test. The omissions and incomplete disclosures by Natera
 13 alleged herein were material in that a reasonable person would attach importance to them and would be
 14 induced to act on the information in making decisions. Reasonable consumers would have been
 15 expected to have relied on Natera's omissions and incomplete disclosures at issue.

16 219. Natera possessed superior knowledge regarding the accuracy and reliability of its NIPT
 17 tests, which was not reasonably discoverable by Plaintiff Delaurie, Illinois Subclass members, or their
 18 treating physicians.

19 220. As a direct and proximate result of Natera's deceptive and unfair acts and practices,
 20 Plaintiff Delaurie and Illinois Subclass members sustained ascertainable losses in that Plaintiff Delaurie
 21 and Illinois Subclass members would not have paid for the Panorama NIPT tests or would have paid
 22 significantly less for them but for Natera's omissions of material fact. Among other injuries, Plaintiff
 23 Delaurie and Illinois Subclass members overpaid for their NIPT tests and did not receive the value they
 24 reasonably expected and bargained for.

25 221. Natera knew or should have known that its omissions and incomplete disclosures of fact
 26 were false and misleading, and intended for consumers to rely on them.

222. Accordingly, pursuant to 815 Ill. Comp. Stat. § 505/10a(a), Plaintiff Delaurie and the Illinois Subclass are entitled to compensatory damages, punitive damages under 815 Ill. Comp. Stat. § 505/10a(c), injunctive relief, and reasonable attorneys' fees.

COUNT V

Violation of the Florida Deceptive and Unfair Practices Act (Fla. Stat. §§ 501.201 *et seq.*)

223. Plaintiffs incorporate and reallege the foregoing allegations of fact.

224. Plaintiff Law brings this claim on behalf of herself and the Florida Subclass.

225. Plaintiff Law and Florida Subclass members are “consumers” within the meaning of the Florida Unfair and Deceptive and Unfair Trade Practices Act (“FDUTPA”), Fla. Stat. § 501.203(7).

226. Defendant is engaged in “trade or commerce” within the meaning of Fla. Stat. § 501.203(8).

227. The FDUTPA prohibits “[u]nfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce.” Fla. Stat. § 501.204(1). Defendant engaged in unfair and deceptive trade practices that violate the FDUTPA.

228. Natera engaged in unfair acts and practices by developing and selling Panorama NIPT tests that were inaccurate and unreliable to test for a variety of genetic abnormalities. Natera derived a substantial financial benefit from its sale of these tests.

229. Natera engaged in deceptive and unfair practices by omitting material information for purposes of inducing consumers to purchase and submit to Natera for prenatal testing services. Natera actively suppressed and failed to disclose material facts concerning the accuracy and reliability of its NIPT test, including:

- (a) knowingly and intentionally concealing from Plaintiffs, Class members, and their physicians the fact that the Panorama test is widely inaccurate for many rare disorders, is highly susceptible to false positives, and cannot be relied on to make critical decisions during a pregnancy;
- (b) failing to disclose that the PPV for rare but serious conditions such as Trisomy 13, Monosomy X, and DiGeorge Syndrome is much lower, sometimes as low as 2-5%;

- (c) failing to reveal that for rare disorders such as DiGeorge syndrome, there is actually an 80% or greater chance a positive result is wrong; and
- (d) failing to disclose the high risk of false positives.

230. Natera omitted such material facts for purposes of inducing consumers to purchase and submit to Natera for prenatal testing services.

231. Natera knew that its NIPT test is inaccurate and unreliable, and that it was thus committing deceptive acts and practices. Plaintiff Law and the Florida Subclass were deceived by Defendant's omissions into believing that the Panorama NIPT tests were highly accurate and reliable to test for a variety of rare genetic conditions, when in reality the tests generate an unreasonably high number of false positive results and cannot be relied upon to make important pregnancy decisions.

232. Natera owed Plaintiff Law and Florida Subclass members a duty to disclose these facts because Natera had exclusive and superior knowledge of them; because they would be material to reasonable consumers; and because Natera intended for consumers to rely on the omissions in question.

233. Natera could have readily disclosed the truth regarding its Panorama NIPT tests to Plaintiff Law and Florida Subclass members through various sources, including its website, product brochures and marketing materials, and through Plaintiff Law's and Florida Subclass members' physicians and health care providers.

234. Reasonable consumers, including Plaintiff Law and the Florida Subclass, would have found it material to their purchasing decisions that Natera's products (i) were not reasonably accurate or reliable, (ii) have a low positive predictive value, (iii) were not diagnostic tests, and (iv) cannot replace diagnostic tests. Knowledge of these facts would have been a substantial factor in Plaintiff Law's and the Florida Subclass's decisions to purchase Natera's products. But Defendant did not disclose these material facts.

235. Natera's unfair or deceptive acts or practices were likely to deceive reasonable consumers, including Plaintiff Law and the Florida Subclass, about the true nature of the Panorama NIPT tests that Natera manufactures, advertises, sells, and distributes.

236. Plaintiff Law and the Florida Subclass suffered ascertainable loss caused by Natera's material omissions and misleading incomplete disclosures of facts. But for Natera's deceptive and

unfair conduct, Plaintiff Law and the Florida Subclass would not have purchased the Panorama NIPT tests.

237. As a direct and proximate result of Defendant's FDUTPA violations, Plaintiff Law and the Florida Subclass suffered injury in fact and actual damages.

238. Plaintiff Law and the Florida Subclass also seek an order pursuant to Fla. Stat. § 501.211 enjoining Defendant's unfair, unlawful, and/or deceptive practices, declaratory relief, attorneys' fees, and any other just and proper relief available under the FDUTPA.

COUNT VI

Violation of the New Jersey Consumer Fraud Act (N.J.S.A. §§ 56:8-1, *et seq.*)

239. Plaintiffs incorporate and reallege the foregoing allegations of fact.

240. Plaintiff Kreynstein brings this claim on behalf of herself and the New Jersey Subclass.

241. Plaintiff Kreynstein and members of the New Jersey Subclass are consumers who purchased the Panorama NIPT tests for personal use.

242. The New Jersey Consumer Fraud Act (“NJCFA”), N.J.S.A. §§ 56:8-1, *et seq.*, prohibits “[t]he act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice.” N.J.S.A. § 56:8-2.

243. Natera engaged in unconscionable commercial practices, deception, fraud, and/or false pretense by developing and selling Panorama NIPT tests that were inaccurate and unreliable to test for a variety of genetic abnormalities. Natera derived a substantial financial benefit from its sale of these tests.

244. Moreover, Natera also engaged in unconscionable commercial practices, deception, fraud, and/or false pretense by omitting material information for purposes of inducing consumers to purchase and submit to Natera for prenatal testing services. Natera actively suppressed and failed to disclose material facts concerning the accuracy and reliability of its NIPT test, including:

- (a) knowingly and intentionally concealing from Plaintiffs, Class members, and their physicians the fact that the Panorama test is widely inaccurate for many rare disorders, is highly susceptible to false positives, and cannot be relied on to make critical decisions during a pregnancy;
- (b) failing to disclose that the PPV for rare but serious conditions such as Trisomy 13, Monosomy X, and DiGeorge Syndrome is much lower, sometimes as low as 2-5%;
- (c) failing to reveal that for rare disorders such as DiGeorge syndrome, there is actually an 80% or greater chance a positive result is wrong; and
- (d) failing to disclose the high risk of false positives.

245. Natera omitted such material facts for purposes of inducing consumers to purchase and submit to Natera for prenatal testing services. Natera knowingly sold inaccurate and unreliable NIPT tests, made misleading and deceptive claims regarding its NIPT tests, and failed to disclose the complete truth regarding its NIPT tests to consumers and their treating physicians.

246. Natera's conduct was fraudulent and deceptive because the omissions and incomplete disclosures of fact had the capacity, tendency and effect of deceiving or misleading reasonable consumers and did, in fact, deceive and mislead reasonable consumers including the Plaintiffs.

247. Defendant's fraudulent omissions were material to Plaintiff Kreynstein and members of the New Jersey Subclass. When Plaintiff Kreynstein and members of the New Jersey Subclass purchased their Panorama NIPT tests, they reasonably relied on the natural and legitimate expectation that the Panorama NIPT tests would accurately tell them whether their pregnancies were at a high risk for certain serious genetic conditions. Had Defendant disclosed that the Panorama NIPT tests were unreliable and often inaccurate, Plaintiff Kreynstein and members of the New Jersey Subclass would not have purchased the Panorama NIPT tests or would have paid less for them.

248. Natera could have readily disclosed the truth regarding its Panorama NIPT tests to Plaintiffs and New Jersey Subclass members through various sources, including its website, product brochures and marketing materials, and through Plaintiff Kreynstein's and New Jersey Subclass members' physicians and health care providers.

1 249. Reasonable consumers, including Plaintiff Kreynstein and the New Jersey Subclass,
2 would have found it material to their purchasing decisions that Natera's products (i) were not reasonably
3 accurate or reliable, (ii) have a low positive predictive value, (iii) were not diagnostic tests, and (iv)
4 cannot replace diagnostic tests. Knowledge of these facts would have been a substantial factor in
5 Plaintiff Kreynstein's and the New Jersey Subclass's decisions to purchase Natera's products. But
6 Defendant did not disclose these material facts.

7 250. Natera knowingly failed to disclose the truth regarding Panorama NIPT tests at the time
8 of sale and at all relevant times thereafter.

9 251. Natera owed Plaintiff Kreynstein and New Jersey Subclass members a duty to disclose
10 these facts because Natera had exclusive and superior knowledge of them; because they would be
11 material to reasonable consumers; and because Natera intended for consumers to rely on the omissions
12 in question.

13 252. As a direct and proximate result of Natera's wrongful conduct in violation of the NJCFA,
14 Plaintiff Kreynstein and members of the New Jersey Subclass have suffered and continue to suffer
15 ascertainable loss because, had Plaintiff Kreynstein and members of the New Jersey Subclass known
16 that the Panorama NIPT tests were unreliable and often inaccurate at the time of purchase, they would
17 not have bought the Panorama NIPT tests or would have paid much less for them. Thus, Plaintiff
18 Kreynstein and members of the New Jersey Subclass paid a price premium on account of Defendant's
19 failure to disclose material facts.

20 253. As a result of Defendant's unconscionable, fraudulent, and deceptive conduct, Plaintiff
21 Kreynstein and members of the New Jersey Subclass are entitled to actual damages, treble damages,
22 costs, attorneys' fees, and other damages to be determined at trial. *See* N.J.S.A. § 56:8-19.

23 254. Plaintiff Kreynstein and members of the New Jersey Subclass also seek an order
24 enjoining Defendant's unlawful, fraudulent and/or deceptive practices, and any other just and proper
25 declaratory or equitable relief available under the NJCFA. *See* N.J.S.A. § 56:8-19.

COUNT VII

Violation of New York's General Business Law § 349

255. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

256. Plaintiff Stephens brings this claim individually and on behalf of the members of the proposed New York Subclass against Defendant.

257. New York's Gen. Bus. Law ("GBL") § 349(a) prohibits "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state."

258. GBL Section 349 requires a plaintiff to show that (1) the defendant's deceptive acts were directed at consumers, (2) the acts are misleading in a material way, and (3) the plaintiff has been injured by consequence of them. Section 349 does not require proof of reliance or proof that the defendant intended to mislead consumers.

259. Defendant committed deceptive acts and practices by failing to disclose material facts regarding the Panorama NIPT tests' accuracy and reliability, as described above.

260. These deceptive acts and practices were directed at consumers. These acts and practices, moreover, were misleading in a material way because they fundamentally misrepresent that the Panorama NIPT tests were capable of producing reliable, accurate, and trustworthy screening results. Further, in consequence of Defendant's omissions, Plaintiff Stephens and members of the New York Subclass suffered economic injury because they would not have purchased the Panorama NIPT test, or would have paid substantially less for it, but for Defendant's materially misleading omissions concerning the test's accuracy and reliability.

261. On behalf of herself and the other members of the New York Subclass, Plaintiff Stephens seeks to recover actual damages or fifty dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT VIII

Violation of New York's General Business Law § 350

262. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

1 263. Plaintiff Stephens brings this claim individually and on behalf of the members of the
 2 proposed Subclass against Defendant.

3 264. New York's GBL § 350 prohibits “[f]alse advertising in the conduct of any business,
 4 trade or commerce or in the furnishing of any service in this state.” The statute defines false advertising
 5 as: advertising, including labeling, of a commodity, or of the kind, character, terms or conditions of any
 6 employment opportunity if such advertising is misleading in a material respect. In determining whether
 7 any advertising is misleading, there shall be taken into account (among other things) not only
 8 representations made by statement, word, design, device, sound or any combination thereof, but also the
 9 extent to which the advertising fails to reveal facts material in the light of such representations with
 10 respect to the commodity or employment to which the advertising relates under the conditions
 11 prescribed in said advertisement, or under such conditions as are customary or usual.

12 265. GBL Section 350 requires a plaintiff to show that (1) the defendant's deceptive acts were
 13 directed at consumers, (2) the acts are misleading in a material way, and (3) the plaintiff has been
 14 injured by consequence of them. Section 350 does not require proof of reliance or proof that the
 15 defendant intended to mislead consumers.

16 266. Defendant engaged in consumer-directed conduct that is deceptive or misleading in a
 17 material way and which constitutes false advertising in violation of GBL § 350 by misrepresenting the
 18 qualities and characteristics of the Panorama NIPT test, and failing to disclose the test's inaccuracy and
 19 unreliability.

20 267. The foregoing advertising was directed at consumers and was likely to mislead a
 21 reasonable consumer acting reasonably under the circumstances.

22 268. These omissions have resulted in consumer injury or harm to the public interest.

23 269. Defendant alone possessed the knowledge that the Panorama test was not capable of
 24 producing reliable, accurate, and trustworthy results.

25 270. As a result of Defendant's omissions, Plaintiff Stephens and members of the New York
 26 Subclass suffered economic injury because they would not have purchased the Panorama NIPT, or
 27 would have paid substantially less for it, but for Defendant's omissions concerning the test's accuracy
 28 and reliability.

271. On behalf of herself and other members of the New York Subclass, Plaintiff Stephens
seeks to recover her actual damages or five hundred dollars, whichever is greater, three times actual
damages, and reasonable attorney's fees.

COUNT IX

Breach of Implied Warranty (California law)

272. Plaintiffs incorporate and reallege the foregoing allegations of facts.

273. Plaintiffs bring this claim on behalf of themselves and the Class and state Subclasses under California law.

274. As the manufacturer, designer, marketer, and/or seller of NIPT tests, by operation of law, Natera warranted that its Panorama NIPT tests would, among other things, pass without objection in the trade and are fit for the ordinary purposes for which such goods are used.

275. At all relevant times, Natera's NIPT tests were not in merchantable condition or fit for the ordinary purpose for which prenatal tests are used. The lack of accuracy and reliability render the tests unsuitable for identifying rare abnormalities during pregnancies and making decisions regarding medical treatment, as they frequently produce false positives. The PPV for more rare genetic conditions for which Panorama screens is as low as 2-5%.

276. Plaintiffs, Class members, and their doctors relied on Natera's claims regarding the accuracy and reliability of its NIPT tests in purchasing the tests and making decisions regarding their pregnancy and treatment.

277. Plaintiffs and Class members are the intended third-party beneficiaries of agreements between Natera and their physicians and health insurers. The agreements between Natera and Plaintiffs' and Class members' physicians and health insurers to use Natera's NIPT test for genetic testing were designed and intended for the benefit of Plaintiffs and Class members to make health care decisions. Natera also understood that Plaintiffs and Class members would require that their NIPT tests provide reliable and accurate information regarding genetic abnormalities that may affect their pregnancy and the well-being of their baby. Natera delivered its NIPT tests to Plaintiffs and Class members understanding the need to meet these requirements.

278. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiffs and Class members have been damaged in an amount to be proven at trial.

COUNT X

Breach of Implied Warranty (Florida law)

279. Plaintiffs incorporate and reallege the foregoing allegations of facts.

280. Plaintiff Law brings this claim on behalf of herself and the Florida Subclass under Florida law.

281. As the manufacturer, designer, marketer, and/or seller of NIPT tests, by operation of law, Natera warranted that its Panorama NIPT tests would, among other things, pass without objection in the trade and are fit for the ordinary purposes for which such goods are used.

282. At all relevant times, Natera's NIPT tests were not in merchantable condition or fit for the ordinary purpose for which prenatal tests are used. The lack of accuracy and reliability render the tests unsuitable for identifying rare abnormalities during pregnancies and making decisions regarding medical treatment, as they frequently produce false positives. The PPV for more rare genetic conditions for which Panorama screens is as low as 2-5%.

283. Plaintiff Law, Florida Subclass members, and their doctors relied on Natera's claims regarding the accuracy and reliability of its NIPT tests in purchasing the tests and making decisions regarding their pregnancy and treatment.

284. Plaintiff Law and Florida Subclass members are the intended third-party beneficiaries of agreements between Natera and their physicians and health insurers. The agreements between Natera and Plaintiff Law's and Florida Subclass members' physicians and health insurers to use Natera's NIPT test for genetic testing were designed and intended for the benefit of Plaintiff Law and Florida Subclass members to make health care decisions. Natera also understood that Plaintiff Law and Florida Subclass members would require that their NIPT tests provide reliable and accurate information regarding genetic abnormalities that may affect their pregnancy and the well-being of their baby. Natera delivered its NIPT tests to Plaintiff Law and Florida Subclass members understanding the need to meet these requirements.

285. Plaintiff Law was excused from providing Natera with notice and opportunity to cure the breach because it would have been futile. Natera has long been aware that the inaccuracy and unreliability of its Panorama NIPT tests render the tests unsuitable for identifying rare abnormalities during pregnancies and making decisions regarding medical treatment. Plaintiff had no reason to believe Natera could have improved the accuracy and reliability of these tests, had she contacted Natera.

286. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiff Law and Florida Subclass members have been damaged in an amount to be proven at trial.

COUNT XI

Breach of Implied Warranty (Illinois law)

287. Plaintiffs incorporate and reallege the foregoing allegations of facts.

288. Plaintiff Delaurie brings this claim on behalf of herself and the Illinois Subclass under Illinois law.

289. As the manufacturer, designer, marketer, and/or seller of NIPT tests, by operation of law, Natera warranted that its Panorama NIPT tests would, among other things, pass without objection in the trade and are fit for the ordinary purposes for which such goods are used.

290. At all relevant times, Natera's NIPT tests were not in merchantable condition or fit for the ordinary purpose for which prenatal tests are used. The lack of accuracy and reliability render the tests unsuitable for identifying rare abnormalities during pregnancies and making decisions regarding medical treatment, as they frequently produce false positives. The PPV for more rare genetic conditions for which Panorama screens is as low as 2-5%.

291. Plaintiff Delaurie, Illinois Subclass members, and their doctors relied on Natera's claims regarding the accuracy and reliability of its NIPT tests in purchasing the tests and making decisions regarding their pregnancy and treatment.

292. Plaintiff Delaurie and Illinois Subclass members are the intended third-party beneficiaries of agreements between Natera and their physicians and health insurers. The agreements between Natera and Plaintiff Delaurie’s and Illinois Subclass members’ physicians and health insurers to use Natera’s NIPT test for genetic testing were designed and intended for the benefit of Plaintiff Delaurie and Illinois Subclass members to make health care decisions. Natera also understood that Plaintiff Delaurie and

1 Illinois Subclass members would require that their NIPT tests provide reliable and accurate information
 2 regarding genetic abnormalities that may affect their pregnancy and the well-being of their baby. Natera
 3 delivered its NIPT tests to Plaintiff Delaurie and Illinois Subclass members understanding the need to
 4 meet these requirements.

5 293. Plaintiff Delaurie was excused from providing Natera with notice and opportunity to cure
 6 the breach because it would have been futile. Natera has long been aware that the inaccuracy and
 7 unreliability of its Panorama NIPT tests render the tests unsuitable for identifying rare abnormalities
 8 during pregnancies and making decisions regarding medical treatment. Plaintiff had no reason to believe
 9 Natera could have improved the accuracy and reliability of these tests, had she contacted Natera.

10 294. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiff
 11 Delaurie and Illinois Subclass members have been damaged in an amount to be proven at trial.

12 **COUNT XII**

13 **Breach of Implied Warranty (Maryland law)**

14 295. Plaintiffs incorporate and reallege the foregoing allegations of facts.

15 296. Plaintiff Heryla brings this claim on behalf of herself and the Maryland Subclass under
 16 Maryland law.

17 297. As the manufacturer, designer, marketer, and/or seller of NIPT tests, by operation of law,
 18 Natera warranted that its Panorama NIPT tests would, among other things, pass without objection in the
 19 trade and are fit for the ordinary purposes for which such goods are used.

20 298. At all relevant times, Natera's NIPT tests were not in merchantable condition or fit for
 21 the ordinary purpose for which prenatal tests are used. The lack of accuracy and reliability render the
 22 tests unsuitable for identifying rare abnormalities during pregnancies and making decisions regarding
 23 medical treatment, as they frequently produce false positives. The PPV for more rare genetic conditions
 24 for which Panorama screens is as low as 2-5%.

25 299. Plaintiff Heryla, Maryland Subclass members, and their doctors relied on Natera's claims
 26 regarding the accuracy and reliability of its NIPT tests in purchasing the tests and making decisions
 27 regarding their pregnancy and treatment.

300. Plaintiff Heryla and Maryland Subclass members are the intended third-party beneficiaries of agreements between Natera and their physicians and health insurers. The agreements between Natera and Plaintiff Heryla's and Maryland Subclass members' physicians and health insurers to use Natera's NIPT test for genetic testing were designed and intended for the benefit of Plaintiff Heryla and Maryland Subclass members to make health care decisions. Natera also understood that Plaintiff Heryla and Maryland Subclass members would require that their NIPT tests provide reliable and accurate information regarding genetic abnormalities that may affect their pregnancy and the well-being of their baby. Natera delivered its NIPT tests to Plaintiff Heryla and Maryland Subclass members understanding the need to meet these requirements.

301. Plaintiff Heryla was excused from providing Natera with notice and opportunity to cure the breach because it would have been futile. Natera has long been aware that the inaccuracy and unreliability of its Panorama NIPT tests render the tests unsuitable for identifying rare abnormalities during pregnancies and making decisions regarding medical treatment. Plaintiff had no reason to believe Natera could have improved the accuracy and reliability of these tests, had she contacted Natera.

302. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiff Heryla and Maryland Subclass members have been damaged in an amount to be proven at trial.

COUNT XIII

Breach of Implied Warranty (New Jersey law)

303. Plaintiffs incorporate and reallege the foregoing allegations of facts.

304. Plaintiff Kreynstein brings this claim on behalf of herself and the New Jersey Subclass under New Jersey law.

305. As the manufacturer, designer, marketer, and/or seller of NIPT tests, by operation of law, Natera warranted that its Panorama NIPT tests would, among other things, pass without objection in the trade and are fit for the ordinary purposes for which such goods are used.

306. At all relevant times, Natera's NIPT tests were not in merchantable condition or fit for the ordinary purpose for which prenatal tests are used. The lack of accuracy and reliability render the tests unsuitable for identifying rare abnormalities during pregnancies and making decisions regarding

1 medical treatment, as they frequently produce false positives. The PPV for more rare genetic conditions
 2 for which Panorama screens is as low as 2-5%.

3 307. Plaintiff Kreynstein, New Jersey Subclass members, and their doctors relied on Natera's
 4 claims regarding the accuracy and reliability of its NIPT tests in purchasing the tests and making
 5 decisions regarding their pregnancy and treatment.

6 308. Plaintiff Kreynstein and New Jersey Subclass members are the intended third-party
 7 beneficiaries of agreements between Natera and their physicians and health insurers. The agreements
 8 between Natera and Plaintiff Kreynstein's and New Jersey Subclass members' physicians and health
 9 insurers to use Natera's NIPT test for genetic testing were designed and intended for the benefit of
 10 Plaintiff Kreynstein and New Jersey Subclass members to make health care decisions. Natera also
 11 understood that Plaintiff Kreynstein and New Jersey Subclass members would require that their NIPT
 12 tests provide reliable and accurate information regarding genetic abnormalities that may affect their
 13 pregnancy and the well-being of their baby. Natera delivered its NIPT tests to Plaintiff Kreynstein and
 14 New Jersey Subclass members understanding the need to meet these requirements.

15 309. Plaintiff Kreynstein was excused from providing Natera with notice and opportunity to
 16 cure the breach because it would have been futile. Natera has long been aware that the inaccuracy and
 17 unreliability of its Panorama NIPT tests render the tests unsuitable for identifying rare abnormalities
 18 during pregnancies and making decisions regarding medical treatment. Plaintiff had no reason to believe
 19 Natera could have improved the accuracy and reliability of these tests, had she contacted Natera.

20 310. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiff
 21 Kreynstein and New Jersey Subclass members have been damaged in an amount to be proven at trial.

22 **COUNT XIV**

23 **Breach of Implied Warranty (New York law)**

24 311. Plaintiffs incorporate and reallege the foregoing allegations of facts.

25 312. Plaintiff Stephens brings this claim on behalf of herself and the New York Subclass under
 26 New York law.

1 313. As the manufacturer, designer, marketer, and/or seller of NIPT tests, by operation of law,
 2 Natera warranted that its Panorama NIPT tests would, among other things, pass without objection in the
 3 trade and are fit for the ordinary purposes for which such goods are used.

4 314. At all relevant times, Natera's NIPT tests were not in merchantable condition or fit for
 5 the ordinary purpose for which prenatal tests are used. The lack of accuracy and reliability render the
 6 tests unsuitable for identifying rare abnormalities during pregnancies and making decisions regarding
 7 medical treatment, as they frequently produce false positives. The PPV for more rare genetic conditions
 8 for which Panorama screens is as low as 2-5%.

9 315. Plaintiff Stephens, New York Subclass members, and their doctors relied on Natera's
 10 claims regarding the accuracy and reliability of its NIPT tests in purchasing the tests and making
 11 decisions regarding their pregnancy and treatment.

12 316. Plaintiff Stephens and New York Subclass members are the intended third-party
 13 beneficiaries of agreements between Natera and their physicians and health insurers. The agreements
 14 between Natera and Plaintiff Stephens's and New York Subclass members' physicians and health
 15 insurers to use Natera's NIPT test for genetic testing were designed and intended for the benefit of
 16 Plaintiff Stephens and New York Subclass members to make health care decisions. Natera also
 17 understood that Plaintiff Stephens and New York Subclass members would require that their NIPT tests
 18 provide reliable and accurate information regarding genetic abnormalities that may affect their
 19 pregnancy and the well-being of their baby. Natera delivered its NIPT tests to Plaintiff Stephens and
 20 New York Subclass members understanding the need to meet these requirements.

21 317. Plaintiff Stephens was excused from providing Natera with notice and opportunity to cure
 22 the breach because it would have been futile. Natera has long been aware that the inaccuracy and
 23 unreliability of its Panorama NIPT tests render the tests unsuitable for identifying rare abnormalities
 24 during pregnancies and making decisions regarding medical treatment. Plaintiff had no reason to believe
 25 Natera could have improved the accuracy and reliability of these tests, had she contacted Natera.

26 318. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiff
 27 Stephens and New York Subclass members have been damaged in an amount to be proven at trial.
 28

COUNT XV

Breach of Implied Warranty (Ohio law)

319. Plaintiffs incorporate and reallege the foregoing allegations of facts.

320. Plaintiff Davis brings this claim on behalf of herself and the Ohio Subclass under Ohio law.

321. As the manufacturer, designer, marketer, and/or seller of NIPT tests, by operation of law, Natera warranted that its Panorama NIPT tests would, among other things, pass without objection in the trade and are fit for the ordinary purposes for which such goods are used.

322. At all relevant times, Natera's NIPT tests were not in merchantable condition or fit for the ordinary purpose for which prenatal tests are used. The lack of accuracy and reliability render the tests unsuitable for identifying rare abnormalities during pregnancies and making decisions regarding medical treatment, as they frequently produce false positives. The PPV for more rare genetic conditions for which Panorama screens is as low as 2-5%.

323. Plaintiff Davis, Ohio Subclass members, and their doctors relied on Natera's claims regarding the accuracy and reliability of its NIPT tests in purchasing the tests and making decisions regarding their pregnancy and treatment.

324. Plaintiff Davis and Ohio Subclass members are the intended third-party beneficiaries of agreements between Natera and their physicians and health insurers. The agreements between Natera and Plaintiff Davis's and Ohio Subclass members' physicians and health insurers to use Natera's NIPT test for genetic testing were designed and intended for the benefit of Plaintiff Davis and Ohio Subclass members to make health care decisions. Natera also understood that Plaintiff Davis and Ohio Subclass members would require that their NIPT tests provide reliable and accurate information regarding genetic abnormalities that may affect their pregnancy and the well-being of their baby. Natera delivered its NIPT tests to Plaintiff Davis and Ohio Subclass members understanding the need to meet these requirements.

325. Plaintiff Davis was excused from providing Natera with notice and opportunity to cure the breach because it would have been futile. Natera has long been aware that the inaccuracy and unreliability of its Panorama NIPT tests render the tests unsuitable for identifying rare abnormalities

1 during pregnancies and making decisions regarding medical treatment. Plaintiff had no reason to believe
2 Natera could have improved the accuracy and reliability of these tests, had she contacted Natera.

3 326. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiff
4 Davis and Ohio Subclass members have been damaged in an amount to be proven at trial.

5 **COUNT XVI**

6 **Unjust Enrichment (California law)**

7 327. Plaintiffs incorporate and reallege the foregoing allegations of fact.

8 328. This equitable count is pled in the alternative to Plaintiffs' claims at law.

9 329. Plaintiffs bring this claim on behalf of themselves and the Class and state Subclasses
10 under California law.

11 330. Plaintiffs and Class members lack an adequate remedy at law.

12 331. As the intended and expected result of its conscious wrongdoing, Natera has profited and
13 benefitted from Plaintiffs and Class members' purchases of Panorama NIPT tests.

14 332. Natera has voluntarily accepted and retained these profits and benefits, knowing that, as a
15 result of its misconduct alleged herein, Plaintiffs and the Class were not receiving accurate test results an
16 ordinary consumer would expect. Plaintiffs and Class members reasonably expected that when they
17 purchased a Panorama NIPT test, they would be able to rely on the results to make potentially life-
18 altering decisions regarding their pregnancy and their course of treatment.

19 333. Natera has been unjustly enriched by its deceptive, wrongful, and unscrupulous conduct
20 and by its withholding of benefits and unearned monies from Plaintiffs and the Class rightfully
21 belonging to them. Equity and good conscience militate against permitting Natera to retain these profits
22 and benefits from its wrongful conduct. They should accordingly be disgorged or placed in a
23 constructive trust so that Plaintiffs and Class members can obtain restitution.

24 **COUNT XVII**

25 **Unjust Enrichment (Florida law)**

26 334. Plaintiffs incorporate and reallege the foregoing allegations of fact.

27 335. This equitable count is pled in the alternative to Plaintiffs' claims at law.

1 336. Plaintiff Law brings this claim on behalf of herself and the Florida Subclass under Florida
2 law.

3 337. Plaintiff Law and Florida Subclass members lack an adequate remedy at law.

4 338. As the intended and expected result of its conscious wrongdoing, Natera has profited and
5 benefitted from Plaintiff Law and Florida Subclass members' purchases of Panorama NIPT tests.

6 339. Natera has voluntarily accepted and retained these profits and benefits, knowing that, as a
7 result of its misconduct alleged herein, Plaintiff Law and the Florida Subclass were not receiving
8 accurate test results an ordinary consumer would expect. Plaintiff Law and Florida Subclass members
9 reasonably expected that when they purchased a Panorama NIPT test, they would be able to rely on the
10 results to make potentially life-altering decisions regarding their pregnancy and their course of
11 treatment.

12 340. Natera has been unjustly enriched by its deceptive, wrongful, and unscrupulous conduct
13 and by its withholding of benefits and unearned monies from Plaintiff Law and the Florida Subclass
14 rightfully belonging to them. Equity and good conscience militate against permitting Natera to retain
15 these profits and benefits from its wrongful conduct. They should accordingly be disgorged or placed in
16 a constructive trust so that Plaintiff Law and Florida Subclass members can obtain restitution.

17 **COUNT XVIII**

18 **Unjust Enrichment (Illinois law)**

19 341. Plaintiffs incorporate and reallege the foregoing allegations of fact.

20 342. This equitable count is pled in the alternative to Plaintiffs' claims at law.

21 343. Plaintiff Delaurie brings this claim on behalf of herself and the Illinois Subclass under
22 Illinois law.

23 344. Plaintiff Delaurie and Illinois Subclass members lack an adequate remedy at law.

24 345. As the intended and expected result of its conscious wrongdoing, Natera has profited and
25 benefitted from Plaintiff Delaurie and Illinois Subclass members' purchases of Panorama NIPT tests.

26 346. Natera has voluntarily accepted and retained these profits and benefits, knowing that, as a
27 result of its misconduct alleged herein, Plaintiff Delaurie and the Illinois Subclass were not receiving
28 accurate test results an ordinary consumer would expect. Plaintiff Delaurie and Illinois Subclass

members reasonably expected that when they purchased a Panorama NIPT test, they would be able to rely on the results to make potentially life-altering decisions regarding their pregnancy and their course of treatment.

347. Natera has been unjustly enriched by its deceptive, wrongful, and unscrupulous conduct and by its withholding of benefits and unearned monies from Plaintiff Delaurie and the Illinois Subclass rightfully belonging to them. Equity and good conscience militate against permitting Natera to retain these profits and benefits from its wrongful conduct. They should accordingly be disgorged or placed in a constructive trust so that Plaintiff Delaurie and Illinois Subclass members can obtain restitution.

COUNT XIX

Unjust Enrichment (Maryland law)

348. Plaintiffs incorporate and reallege the foregoing allegations of fact.

349. This equitable count is pled in the alternative to Plaintiffs' claims at law.

350. Plaintiff Heryla brings this claim on behalf of herself and the Maryland Subclass under Maryland law.

351. Plaintiff Heryla and Maryland Subclass members lack an adequate remedy at law.

352. As the intended and expected result of its conscious wrongdoing, Natera has profited and benefitted from Plaintiff Heryla and Maryland Subclass members' purchases of Panorama NIPT tests.

353. Natera has voluntarily accepted and retained these profits and benefits, knowing that, as a result of its misconduct alleged herein, Plaintiff Heryla and the Maryland Subclass were not receiving accurate test results an ordinary consumer would expect. Plaintiff Heryla and Maryland Subclass members reasonably expected that when they purchased a Panorama NIPT test, they would be able to rely on the results to make potentially life-altering decisions regarding their pregnancy and their course of treatment.

354. Natera has been unjustly enriched by its deceptive, wrongful, and unscrupulous conduct and by its withholding of benefits and unearned monies from Plaintiff Heryla and the Maryland Subclass rightfully belonging to them. Equity and good conscience militate against permitting Natera to retain these profits and benefits from its wrongful conduct. They should accordingly be disgorged or placed in a constructive trust so that Plaintiff Heryla and Maryland Subclass members can obtain restitution.

COUNT XX

Unjust Enrichment (New Jersey law)

355. Plaintiffs incorporate and reallege the foregoing allegations of fact.

356. This equitable count is pled in the alternative to Plaintiffs' claims at law.

357. Plaintiff Kreynstein brings this claim on behalf of herself and the New Jersey Subclass under New Jersey law.

358. Plaintiff Kreynstein and New Jersey Subclass members lack an adequate remedy at law.

359. As the intended and expected result of its conscious wrongdoing, Natera has profited and benefitted from Plaintiff Kreynstein and New Jersey Subclass members' purchases of Panorama NIPT tests.

360. Natera has voluntarily accepted and retained these profits and benefits, knowing that, as a result of its misconduct alleged herein, Plaintiff Kreynstein and the New Jersey Subclass were not receiving accurate test results an ordinary consumer would expect. Plaintiff Kreynstein and New Jersey Subclass members reasonably expected that when they purchased a Panorama NIPT test, they would be able to rely on the results to make potentially life-altering decisions regarding their pregnancy and their course of treatment.

361. Natera has been unjustly enriched by its deceptive, wrongful, and unscrupulous conduct and by its withholding of benefits and unearned monies from Plaintiff Kreynstein and the New Jersey Subclass rightfully belonging to them. Equity and good conscience militate against permitting Natera to retain these profits and benefits from its wrongful conduct. They should accordingly be disgorged or placed in a constructive trust so that Plaintiff Kreynstein and New Jersey Subclass members can obtain restitution.

COUNT XXI

Unjust Enrichment (New York law)

362. Plaintiffs incorporate and reallege the foregoing allegations of fact.

363. This equitable count is pled in the alternative to Plaintiffs' claims at law.

364. Plaintiff Stephens brings this claim on behalf of herself and the New York Subclass under New York law.

1 365. Plaintiff Stephens and New York Subclass members lack an adequate remedy at law.

2 366. As the intended and expected result of its conscious wrongdoing, Natera has profited and
3 benefitted from Plaintiff Stephens and New York Subclass members' purchases of Panorama NIPT tests.

4 367. Natera has voluntarily accepted and retained these profits and benefits, knowing that, as a
5 result of its misconduct alleged herein, Plaintiff Stephens and the New York Subclass were not receiving
6 accurate test results an ordinary consumer would expect. Plaintiff Stephens and New York Subclass
7 members reasonably expected that when they purchased a Panorama NIPT test, they would be able to
8 rely on the results to make potentially life-altering decisions regarding their pregnancy and their course
9 of treatment.

10 368. Natera has been unjustly enriched by its deceptive, wrongful, and unscrupulous conduct
11 and by its withholding of benefits and unearned monies from Plaintiff Stephens and the New York
12 Subclass rightfully belonging to them. Equity and good conscience militate against permitting Natera to
13 retain these profits and benefits from its wrongful conduct. They should accordingly be disgorged or
14 placed in a constructive trust so that Plaintiff Stephens and New York Subclass members can obtain
15 restitution.

16 **COUNT XXII**

17 **Unjust Enrichment (Ohio law)**

18 369. Plaintiffs incorporate and reallege the foregoing allegations of fact.

19 370. This equitable count is pled in the alternative to Plaintiffs' claims at law.

20 371. Plaintiff Davis brings this claim on behalf of herself and the Ohio Subclass under Ohio
21 law.

22 372. Plaintiff Davis and Ohio Subclass members lack an adequate remedy at law.

23 373. As the intended and expected result of its conscious wrongdoing, Natera has profited and
24 benefitted from Plaintiff Davis and Ohio Subclass members' purchases of Panorama NIPT tests.

25 374. Natera has voluntarily accepted and retained these profits and benefits, knowing that, as a
26 result of its misconduct alleged herein, Plaintiff Davis and the Ohio Subclass were not receiving
27 accurate test results an ordinary consumer would expect. Plaintiff Davis and Ohio Subclass members
28 reasonably expected that when they purchased a Panorama NIPT test, they would be able to rely on the

1 results to make potentially life-altering decisions regarding their pregnancy and their course of
 2 treatment.

3
 4 375. Natera has been unjustly enriched by its deceptive, wrongful, and unscrupulous conduct
 5 and by its withholding of benefits and unearned monies from Plaintiff Davis and the Ohio Subclass
 6 rightfully belonging to them. Equity and good conscience militate against permitting Natera to retain
 7 these profits and benefits from its wrongful conduct. They should accordingly be disgorged or placed in
 8 a constructive trust so that Plaintiff Davis and Ohio Subclass members can obtain restitution.

9 **VIII. PRAYER FOR RELIEF**

10 WHEREFORE, Plaintiffs, on behalf of themselves and the members of the Class, respectfully
 11 request that this Court:

- 12 (a) Determine that the claims alleged herein may be maintained as a class action under Rule
 13 23 of the Federal Rules of Civil Procedure, and issue an order certifying the Class and
 14 Subclasses as defined above and appoint Plaintiffs as representative of the Class and
 15 Subclasses and their counsel as Class Counsel;
- 16 (b) Award all actual, general, special, incidental, statutory, punitive, and consequential
 17 damages to which Plaintiffs and Class members are entitled;
- 18 (c) Award pre-judgment and post-judgment interest on such monetary relief;
- 19 (d) Grant appropriate injunctive and/or declaratory relief, including, without limitation, an
 20 order enjoining Natera from continuing the wrongful, deceptive, and unfair business
 21 practices described in this Complaint;
- 22 (e) Award reasonable attorneys' fees and costs as provided by law; and
- 23 (f) Grant such further and other relief that this Court deems appropriate.

24 **IX. DEMAND FOR JURY TRIAL**

25 Plaintiffs hereby demand a trial by jury for all claims so triable.

26 Dated: April 27, 2023

27 By: /s/ L. Timothy Fisher
 L. Timothy Fisher

28 **BURSOR & FISHER, P.A.**
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10 Dated: April 27, 2023

11 By: /s/ Dena C. Sharp

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